

EXHIBIT A

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: NEW ENGLAND COMPOUNDING
PHARMACY, INC. PRODUCTS LIABILITY
LITIGATION

MDL No. 2419

Master Dkt. 1:13-md-02419-RWZ

THIS DOCUMENT RELATES TO:

All Actions

**LEAD COUNSEL’S MOTION FOR
APPROVAL OF AGREEMENT BETWEEN THE TORT TRUSTEE AND THE
CENTERS FOR MEDICARE AND MEDICAID SERVICES REGARDING
RESOLUTION OF CLAIMS FOR REIMBURSEMENT OF HEALTH CARE COSTS**

On July 28, 2016, Lead Counsel for the Plaintiffs’ Steering Committee (“Lead Counsel”) made a report to the Court concerning the status of claims processing and attempts by the Court-appointed Tort Trustee, Lynne Riley (“Tort Trustee”), with the aid of Lead Counsel and others, to resolve claims for medical cost reimbursement asserted against victims’ recoveries from the Tort Trust in the NECC Bankruptcy Settlement by the Centers for Medicare and Medicaid Services (“CMS”). Lead Counsel reported that the Tort Trustee had reached an agreement in principle with CMS and that the draft agreement was under consideration by the United States Department of Justice (“DOJ”). Finalization and signature of that agreement awaits DOJ approval. A copy of the final draft agreement under consideration by the DOJ is attached hereto as Exhibit A.

The agreement provides tangible benefits to Claimants in the Bankruptcy Settlement.

These include:

- The ability to resolve all claims by CMS for health cost reimbursement using a simple and easily administered formula;
- Utilization of criteria already approved by the Bankruptcy Court and already applied to each Claimant by the Court-appointed Claims Administrator to establish the total amount a Claimant would pay to resolve CMS’s claim – from a

low of 10% to a high of 21.5% of their settlement payments – with only a handful of claimants paying more than 15%;

- A nine month limit (between September 1, 2012 and May 31, 2013) for Medicare eligibility of Claimants, outside of which CMS has agreed not to pursue claims for health cost reimbursement;
- A waiver by CMS of any potential claim against Claimants in the lowest injury category (Category VII);
- The ability to resolve Medicare’s claim as well as claims for health cost reimbursement from many large insurers for the same percentage amount –rather than negotiate with two different lienholders;
- An ability, by the vast majority of Claimants, to opt-out of the resolution program and negotiate resolution of CMS’s claims on their own if they so choose; and
- For those Claimants who seek to opt-out of the resolution program and negotiate CMS’s claim individually, CMS will designate a special contact person at its Benefit Coordination & Recovery Center to negotiate CMS’s claims.

Nothing in the agreement requires or suggests that while the agreement is pending approval by this Court or the DOJ CMS should refrain from providing information to Claimants or their attorneys concerning CMS’s claim for medical cost reimbursement.

In the interest of expediting the necessary Court approval (and thus expediting payment to victims), Lead Counsel files this motion for approval of the agreement while formal approval of the terms of the agreement are still under consideration by the DOJ. This Court has set a telephonic hearing for August 16, 2016, at 2:00 p.m., to consider the agreement with CMS. We have invited representatives of CMS and DOJ to participate. A proposed order approving the agreement with CMS is attached hereto as Exhibit B.

I. The Tort Trustee’s Obligations Concerning CMS Claims for Medical Cost Reimbursement

The Third Amended Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc. [MDL Dkt. No. 1352-1] (the “NECC Plan”) provides that the Tort Trustee is responsible for

all reimbursement and reporting obligations imposed by the Medicare Act¹ for repayment of any NECC related conditional payments made by CMS under Medicare Part A, B, C and D.² The Plan specifically provides that the Tort Trustee should attempt to enter into a global resolution with CMS to reimburse or otherwise resolve all Medicare claims for medical cost reimbursement as required by federal statute.³ The Plan also provides that if a global resolution with CMS cannot be reached, before distribution of any funds from the Tort Trust to any Claimant, the Tort Trustee must, among other obligations, comply with all formal notice requirements under federal statute, provide notice of any potential CMS claim to the Claimant and, failing the Claimant's resolution of CMS's claim within 120 days of that notice, the Tort Trustee is obligated to ensure that CMS's claim is resolved before making payment to the Claimant.⁴

The purpose of entering into a global settlement with CMS is twofold. First, such an agreement provides administrative efficiencies. Under such an agreement a simple mechanism can be established to resolve each of CMS's claims for medical cost reimbursement without the time and effort involved in having each Claimant, their attorney, or a lien resolution professional individually negotiate with CMS. Such an agreement also alleviates the need for CMS personnel to search claims data on individual claimants and determine which services are related to injuries suffered from exposure to a NECC contaminated product and negotiate the proper amount of CMS's claim. This savings in time and effort directly translates into the second purpose of such a resolution – to pass onto the Claimant the savings that come from administrative efficiency. The money that would otherwise be used to accomplish individual resolution can instead be passed onto the Claimant in the form of higher settlement payments. The benefits of such a

¹ 42 U.S.C. 1395y(b) and 1995y(b)8.

² NECC Plan at 28-29.

³ *Id.*

⁴ *Id.*

global approach are well recognized and global resolution of Medicare's claims are a standard part of almost every MDL settlement involving personal injury claims.⁵

II. The Tort Trustee's Agreement with CMS

The agreement reached between the Tort Trustee and CMS (the "agreement"), if approved, would resolve the vast majority of claims for health care cost reimbursement by CMS. It would resolve CMS's claims for reimbursement for health care coverage provided to victims of the NECC outbreak paid for under Medicare Parts A and B from payments made to Claimants in each of the NECC National Settlement, the Insight Settlement, the Inspira Settlement, the Highpoint Settlement, and the Michigan Pain Specialist Settlement⁶ (collectively, the "Five NECC Settlements"). The agreement is the result of extensive claims analysis and consultation among members of the PSC, a separate lien sub-committee, other plaintiffs' counsel, and the Tort Trustee. It is also the result of a great deal of negotiation with counsel for the DOJ and personnel from CMS over many months. At each step in the process, members of the negotiating team reached out to plaintiffs' counsel, particularly in states with large numbers of Claimants, to seek advice and counsel, to preview various portions of the agreement, and to ensure the agreement would benefit the largest number of Claimants possible.

⁵ See *In re Oil Spill by Oil Rig Deepwater Horizon*, 295 F.R.D. 112, 160-61 (E.D. La. 2013) ("This global resolution program will, if achieved, provide an efficient way to protect the Medicare Program's interests in the settlement funds while also providing significant benefits to Class Members. . . . The global resolution approach has been successfully utilized in almost all MDL settlements involving personal injury claims since 2005.") (internal citations omitted).

⁶ Payments from the MPS Settlement are not made by the Tort Trustee but rather by a separate MPS Settlement Fund Administrator. The MPS class action settlement was approved by a state court in Michigan after the Third Amended Plan of Reorganization was approved by the Bankruptcy Court. Lead counsel in the Michigan class settlement is a Court-appointed member of the PSC in the MDL. Michigan Class Counsel has been involved in the negotiation of the Agreement with CMS and has agreed to seek approval from the Court in Michigan of the Agreement for implementation in the MPS Settlement.

A. The Claim Resolution Matrix

Claimants who participate in the CMS claim resolution program pursuant to the Agreement will be able to resolve CMS's claim for reimbursement of health care costs using a simple formula. Attached as Exhibit C to this motion is a copy of the negotiated Claims Resolution Matrix. Under the Agreement, a Claimant participating in the resolution program would have a portion of each of his/her payments from each of the Five NECC Settlements deducted and paid to CMS. The amount deducted from each Claimant's payment is derived by reference to the Claims Resolution Matrix and range from 10% to 21.5%. If, for example, based on a Claimant's particular circumstances, the Claimant falls into a box on the matrix indicating his or her payment percentage is 10%, then 10% of each payment made to the Claimant by the Tort Trustee or the MPS Settlement Fund Administrator, whether from the National Settlement or one of the four clinic specific settlements, would be deducted and paid to CMS in order to resolve CMS's claim.

The Claims Resolution Matrix is based upon the criteria already approved by the Bankruptcy Court and used by the Court-appointed Claims Administrator to determine payments to Claimants in the NECC National Settlement. As the Court will recall, each Claimant applies for compensation using one of seven categories of injury as set forth in the chart below.⁷

Category	Description	Base Points
Category 1	Death after MPA Injection <i>and</i> (1) Spinal or Paraspinal Fungal Infection ⁸ and/or (2) Fungal Meningitis	55
Category 2	Non-Death Fungal Meningitis <i>and</i> Spinal or Paraspinal Fungal Infection after MPA Injection	40

⁷ A more detailed description of each of the seven injury categories is provided in in the Court Approved Claims Resolution Procedures attached hereto as Exhibit D.

⁸ Including vertebral osteomyelitis, discitis, sacroiliitis, phlegmon, abscess and/or arachnoiditis.

Category 3	Non-Death Fungal Meningitis after MPA Injection	30
Category 4	Non-Death Spinal <i>or</i> Paraspinal Fungal Injection after MPA Injection	20
Category 5	Peripheral Joint Fungal Infection after MPA Injection	10
Category 6	Symptoms of Headache, Word-Finding Difficulty, Nausea/Vomiting, Fever, Neck Stiffness or Pain, Back Pain, Photophobia, Lack of Appetite, Urine Retention, Slurred Speech, Limb Weakness, Numbness and/or Pain at Injection Site <i>and</i> a Lumbar Puncture, MRI or CT Guided Biopsy after MPA Injection	1
Category 7	No Symptoms or No Lumbar Puncture, MRI, or CT Guided Biopsy after MPA Injection	½

Each Claimant qualifying for one of the seven categories is awarded a base point amount, as indicated above, depending upon the category. Category I Claimants receive the highest number of base points and Category VII Claimants receive the lowest.

Within all injury categories (except for Category VII), Claimants can also apply for certain “upward adjustments” to their base points. These adjustments are meant to capture the differences in injury between individuals in the same injury category. Based on the number of base points awarded (depending on injury category) and the number of points awarded for all upward adjustments for which they qualify, the Claimant’s total number of points is calculated and used as a basis for determining the total payment to the Claimant in the NECC Settlement. Each point is assigned a value based on the total number of points awarded to all Claimants and

the total amount available for distribution. The more points awarded, the higher a Claimant's total payment from the Tort Trust.⁹

The Claims Resolution Matrix also uses the Claimant's injury category (Categories I – VII) and the number of points awarded to each claimant for two of the “upward adjustments” to determine the percentage of the Claimant's recovery to be paid to CMS to resolve CMS's claim. In general, the higher the injury category and the higher the number of points awarded for the long term hospitalization adjustment (“LHA”)¹⁰ and for the long term antifungal treatment adjustment (LAFT),¹¹ the larger the percentage of their total recovery a Claimant will pay to resolve CMS's lien. For example, a Category III Claimant who was awarded 4 points for LHA and 3 points for LAFT would pay 12.5% of their total payments from all settlements to resolve CMS's claim.¹²

Of the many upward adjustments available to Claimants in the Court-approved settlement process, LHA and LAFT are most closely associated with higher medical costs. The longer an individual was hospitalized and the longer they were required to be treated with antifungal medication, the higher the medical costs associated with their care. This is not true of other upward adjustments available to Claimants (e.g. age, existence of dependent children, lost income). In this way, the Claims Resolution Matrix takes into account the higher costs associated with medical treatment provided to Claimants with more severe injuries. Claimants

⁹ The procedures for each of the individual clinic settlements are similar. In some instances the procedures for determining points awarded in the clinic settlements are identical to those in the National Settlement. In some instances the clinic settlement procedures may include additional upward adjustments not available in the National Settlement.

¹⁰ The LHA adjustment awards additional points to Claimants based upon the length of time they were hospitalized as a result of their exposure to an NECC contaminated product.

¹¹ The LAFT adjustment awards additional points to Claimants based upon the length of time they were treated with antifungal medication as a result of their exposure to an NECC contaminated product.

¹² A Claimant in Category III is required to pay 11.5% if they received anywhere from 2.5-5 points for long term hospitalization and are required to pay an additional 1% if they received anywhere from 2-5 points for LAFT (11.5% + 1% = 12.5%).

with higher awards for LHA and LAFT are generally awarded a greater number of points under the NECC Settlement procedures, and generally will receive the largest awards from the NECC Settlements. Use of these upward adjustments as a proxy for CMS's expenditures avoids the need for review of individual Claimant's medical records and negotiations over which services paid for by CMS are related to exposure to an NECC product.

B. The time period for which CMS will recover is limited

The Agreement provides that CMS will only seek to recover against those Claimants who were eligible for Medicare (due to age, disability or other reasons) during the period from September 1, 2012 to May 31, 2013. Any Claimant who participates in the resolution program and was not Medicare eligible during this time period, whether they later had medical services paid for by Medicare related to exposure to an NECC product or not, will receive the benefit of the release from CMS included in the Agreement – but will not be required to pay a percentage to CMS under the Claims Resolution Matrix. For example, any Claimant who became Medicare eligible after May 31, 2013, although they may have received medical care covered by Medicare, will pay nothing to CMS to resolve CMS's claim.

C. For Claimants with claims from multiple sources, the Claims Resolution Matrix may cap their liability

The preliminary data obtained by the Tort Trustee on the first 1199 fully approved claims and used, in part, to help develop the Claims Resolution Matrix, indicated that a high percentage of Claimants may be subject to a claim for reimbursement from both Medicare as well as from one (or more) private insurers.¹³ The Tort Trustee, with assistance from Lead Counsel and others, has reached an agreement in principle to resolve the claims for reimbursement by some

¹³ This may occur for several reasons. For instance, someone may have aged onto Medicare (and off a private insurance plan) while being treated for an NECC related illness. That individual would be subject to a claim for health care reimbursement from both his/her private insurer as well as CMS.

large private insurers on the same basis and using the same claims resolution matrix as preliminarily agreed to by CMS. The Agreement with CMS provides that in the cases where a Claimant has both a claim for medical cost reimbursement asserted by CMS and a private insurer who has agreed to participate in a similar arrangement, the percentage payment set forth in the Claims Resolution Matrix will represent a cap on the Claimant's liability. In those situations CMS has agreed to receive only 50% of the total payment called for by the matrix to resolve its claim. The other 50% would be used to satisfy the claim of the private participating insurer. The Claimant would thereby resolve both public and private claims for the same total deduction from their payment.

In situations where the Claimant has a claim for reimbursement from both Medicare and a private insurer with whom the Tort Trustee has no agreement, CMS has agreed to accept 50% of the total payment otherwise called for by the matrix to resolve CMS's claim. The Claimant and/or the Claimant's attorney would be responsible for resolving the remaining private claim through individual negotiations.

D. No Payment Will Be Made to Medicare by Category VII Claimants

Claimants in Category VII will not be required to make any payment to CMS under the Agreement. Whether or not they were Medicare eligible during the applicable time period, they will receive the benefit of the release by CMS under the Agreement with no payment to CMS.

E. The vast majority of Claimants in Categories I-VI will have the option to participate in the resolution program or to resolve CMS's claim on their own

During the negotiation of the Claim Resolution Matrix, Lead Counsel and others reached out to various plaintiffs' counsel with a large number of Claimants and asked them to evaluate the proposed matrix – particularly in terms of whether it would save their client's money when compared to resolution of outstanding Medicare claims on an individual basis. The response was

overwhelmingly positive. However, during this process some counsel expressed preference for the ability to resolve their client's claim, in particular situations, on an individual basis through individual negotiation. To that end, the Agreement provides that all Claimants who are in Categories I-V in the National Settlement have the option to inform the Trustee that they do not wish to participate in the resolution program. Once a Claimant exercises this opt-out right, he or she (or his or her attorney) can individually negotiate with CMS to resolve the claim with respect to all payments from any of the NECC Settlements. This same opt-out right is also afforded to Claimants in the Insight Settlement who are in Category VI.¹⁴

Claimants in Category VI would also have the opportunity to opt-out of the Agreement and pursue individualized negotiations in the situation where they also have a claim for reimbursement from a state Medicaid agency, the Veteran's Administration or TriCare . For those Category VI Claimants who do not have a claim from one of these other sources and therefore are not able to opt-out, the percentage of recovery paid under the matrix is the lowest – 10%. Given the average estimated payments to Category VI claimants in the National Settlement, the impact of this payment is minimal. The average number of total points awarded to Category VI claimants in the National Settlement is 1.5. Thus, the average amount deducted from the Initial Payments made to Category VI claimants in the National Settlement and paid to CMS under the resolution plan approximately \$130.

¹⁴ Because of the procedures for awarding points in the Insight Settlement differ from those in the National Settlement, Claimants in Category VI in the Insight Settlement, in some instances, are receiving substantial awards and thus, would pay substantially more than other Category VI claimants to CMS under the resolution plan. For instance, the Insight Settlement Procedures take into account lost wages. In some instances individuals in Category VI in the Insight Settlement, although receiving few "base points," are receiving substantially more points as a result of lost earnings and might, in some circumstances, pay a disproportionately higher amount to resolve their liens than a Category VI Claimant in the National Settlement. In consultation with counsel for Virginia Claimants it was determined that in order to accommodate these situations, claimants in Category VI in the Insight Settlement should also have the ability to opt-out of the Agreement and resolve CMS's claim individually if they so choose.

III. The Court Should Approve the Agreement with CMS

Lead Counsel, the PSC, and the Tort Trustee urge the Court to approve the proposed Agreement with CMS. The Agreement absolves each Claimant, their attorney, and the Tort Trustee of the statutory reporting obligations imposed by Section III of the Medicare, Medicaid & SCHIP Extension Act of 2007¹⁵ and affords Claimants a simple and quick mechanism to resolve CMS's claims for health care cost reimbursement without further negotiation and on a very favorable basis. For the vast majority of Claimants, and for all the Claimants in Categories I-V who suffered the most serious injury, the resolution offered by the Agreement is wholly voluntary. If for some reason, in a particular situation, the Claimant or their attorney feels that they can negotiate a better deal with CMS, they have the right to opt-out of the Agreement and immediately engage in individual negotiations with CMS to resolve CMS's claim.

During the negotiation process the Claims Resolution Matrix was tested by plaintiffs' counsel from almost all affected states. Counsel with the ten greatest number of clients approved for payment by the Claims Administrator were asked to run their client's potential claims and compare them to the result obtained by use of the proposed matrix. The response was positive and very few instances were identified where application of the matrix did not result in a very favorable resolution for the Claimant.

¹⁵ 42 USC §1395y(b)(8).

For the reasons set forth above, Lead Counsel respectfully requests that the Court enter the attached proposed Order approving the Agreement reached between the Tort Trustee and CMS.

Dated: August 4, 2016

Respectfully submitted,

/s/ Thomas M. Sobol

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Plaintiffs' Steering Committee

CERTIFICATE OF SERVICE

I, Thomas M. Sobol, hereby certify that I caused a copy of the foregoing to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: August 4, 2016

/s/ Thomas M. Sobol

Thomas M. Sobol, BBO # 471770

EXHIBIT A

FOR SETTLEMENT PURPOSES ONLY; CONFIDENTIAL

**TENTATIVE DRAFT SETTLEMENT AGREEMENT, SUBJECT TO
APPROVAL**

This Settlement Agreement ("Agreement") is entered into by and among the United States of America on behalf of the United States Department of Health and Human Services ("HHS") and its Centers for Medicare & Medicaid Services ("CMS"), the NECC Tort Trustee on behalf of the NECC National Settlement Fund, the Insight Settlement Fund, the Inspira Settlement Fund, and the High Point Settlement Fund, and the MPS Class Counsel and the MPS Settlement Fund Administrator on behalf of the MPS Settlement Fund, and the Participating Lienholders. All terms not otherwise defined in the body of this Agreement shall have the meanings set forth in Attachment A.

WHEREAS, CMS has asserted Medicare Secondary Payer ("MSP") claims pursuant to 42 U.S.C. § 1395y(b) against the Five NECC Settlement Funds with respect to Parts A and B Medicare-covered items and services associated with injuries from the administration of NECC products paid and to be paid under Medicare on behalf of Medicare-Entitled Claimants;

WHEREAS, the NECC Tort Trustee and MPS Class Counsel dispute the amount of CMS's MSP claims, and through good faith negotiations, the parties have reached an agreement to resolve this dispute, and their agreement is set forth below;

WHEREAS, Participating Lienholders and certain Non-Participating Lienholders have asserted medical liens against certain Claimants' payments from the Five NECC Settlement Funds as a result of payments made on behalf of GHP-Entitled Claimants for covered items and services associated with injuries from the administration of NECC products;

WHEREAS, the NECC Tort Trustee and MPS Class Counsel believe that it is in the best interests of many GHP-Entitled Claimants to resolve the medical liens asserted by Participating Lienholders so that payments may be made to GHP-Entitled Claimants from the Five Settlement Funds.

WHEREAS, Claimants to the Five NECC Settlement Funds have filed their claims under one of Seven Claims Categories, the values of which have been set according to various factors. For the NECC National Settlement, the National Settlement Administrator determines which claims fall into Injury Categories I, II, III,

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IV, V, VI, or VII. (See Attachment C for a listing of categories and the injuries included in each category.)

WHEREAS, the settlement administrator for each of the Insight Settlement, Inspira Settlement and High Point Settlement determines which claims fall into Injury Categories I, II, III, IV, V, VI or VII for the Insight Settlement, Inspira Settlement, and High Point Settlement;

WHEREAS the MPS Settlement Fund Administrator relies upon the National Settlement Administrator's determinations of which claims fall into Injury Categories I, II, III, IV, V, VI, or VII for the MPS Settlement;

WHEREAS, the NECC Tort Trustee is responsible for making payments to Claimants from the NECC National Settlement Fund, the Insight Settlement Fund, the Inspira Settlement Fund, and the High Point Settlement Fund;

WHEREAS, the MPS Settlement Fund Administrator is responsible for making payments to Claimants from the MPS Settlement Fund, pursuant to the terms of the MPS Settlement and Order authorizing distributions to be obtained from the Circuit Court overseeing the Settlement.

NOW THEREFORE, in consideration of the mutual covenants contained herein, the parties agree as follows:

I. Payments from the Five NECC Settlements to Category VII Claimants

CMS agrees not to pursue any MSP claims for Parts A and B Medicare-covered items and services relating to payments made to any Category VII Claimant from the Five NECC Settlements.

The Participating Lienholders agree to waive any claims and liens on any and all payments made to Category VII Claimants from the Five NECC Settlements.

II. Payments from the Five NECC Settlements to Categories I through VI Claimants

A. Medicare-Entitled Only Claimants with No Primary Lien from a Medical Lienholder: Any Medicare-Entitled Claimant for whom the NECC Tort Trustee or the MPS Settlement Fund Administrator has not received notice of the

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assertion of a Primary Lien by any other Medical Lienholder, shall have deducted from each Settlement Payment made to that Claimant, the Negotiated Lien Payment Amount, as determined by applying the relevant percentage contained in Attachment B (the “Negotiated Lien Payment Amount”). The Negotiated Lien Payment Amount deducted from the Claimant’s Settlement Payments shall be held in reserve by the NECC Tort Trustee and/or the MPS Settlement Fund Administrator and paid to CMS.

CMS shall not receive any payment relating to payments by the Five NECC Settlements on behalf of any Claimant who became Medicare-eligible post May 31, 2013.

B. GHP-Entitled Only Claimants with No Primary Lien from Medicare or Another Medical Lienholder: Any GHP-Entitled Claimant who is not a Medicare-Entitled Claimant and for whom the NECC Tort Trustee or the MPS Settlement Administrator has notice of only a Primary Lien by a Participating Lienholder shall have the Negotiated Lien Payment Amount deducted from all Settlement Payments made to that Claimant. That amount shall be held in reserve by the NECC Tort Trustee and/or the MPS Settlement Fund Administrator and paid to the appropriate Participating Lienholder.

C. Medicare-Entitled Claimants Who Are Also GHP-Entitled Claimants With A Primary Lien From A Participating Lienholder: Any Medicare-Entitled Claimant, for whom the NECC Tort Trustee or the MPS Settlement Fund Administrator also has notice of the assertion of a Primary Lien by a Participating Lienholder shall have the Negotiated Lien Payment Amount deducted from all Settlement Payments made to that Claimant. That amount(s) shall be held in reserve by the NECC Tort Trustee and/or the MPS Settlement Fund Administrator and paid 50% to CMS and 50% to the appropriate Participating Lienholder, and proof of payment to the Participating Lienholder shall be provided to CMS by the Tort Trustee and/or the MPS Settlement Fund Administrator.

D. Medicare-Entitled Claimants With Primary Liens from Non-Participating Lienholders: Any Medicare-Entitled Claimant, for whom the NECC Tort Trustee or the MPS Settlement Fund Administrator also has notice of the assertion of a Primary Lien by a Non-Participating Lienholder, shall have 50% of the Negotiated Lien Payment Amount deducted from all Settlement Payments made to that Claimant. That amount(s) shall be held in reserve by the NECC Tort Trustee and/or the MPS Settlement Fund Administrator and paid to CMS. The Claimant will be responsible for resolving the Non-Participating Lienholder’s lien before any payment may be made to the Claimant from any of the Five Settlement Funds.

FOR SETTLEMENT PURPOSES ONLY; CONFIDENTIAL**III. Reporting Requirements Under 42 USC § 1395 y(b)(8)**

With respect to reporting requirements of Section III of the Medicare, Medicaid & SCHIP Extension Act of 2007, as set forth in 42 USC §1395y(b)(8) and the program instructions established thereunder, the United States and the Participating Lienholders agree that, except for any reporting requirements set forth in this Agreement, any Responsible Reporting Entity, as defined by CMS program instructions, is not required to report with respect to payments made by the Five NECC Settlement Funds paid to Claimants.

IV. Opt-Out Medicare-Entitled Claimants and Opt-Out GHP-Entitled Claimants

Any Medicare-Entitled Claimant or GHP-Entitled Claimant, whose claim 1) has been determined by the NECC Tort Trustee to fall into Injury Categories I, II, III, IV, or V in the National Settlement; 2) has been determined to have a claim asserted by a Medicaid agency, the Veteran's Administration or Tri-Care against their Settlement Payments; or 3) has been determined by the Insight Settlement Administrator to fall into Category I, II, III, IV, V or VI in the Insight Settlement may elect to opt out of this Settlement Agreement. To be effective, a Notice of Lien Opt-Out, completed and signed by the Claimant, must be mailed and postmarked no later than 30 days after being given notice by the NECC Tort Trustee of the Claimant's entitlement to opt-out ("a Timely Notice of Lien Opt-Out"). By electing to opt-out, the Claimant agrees to negotiate individually with CMS and/or the Medical Lienholder to resolve CMS' and/or the Medical Lienholder's claim(s). Such notice may be given by the Claimant immediately after execution of this Agreement without regard to any delay for court approval or otherwise. Once a Claimant submits a Timely Notice of Lien Opt-Out to the NECC Tort Trustee, the Negotiated Lien Payment Amount as reflected in Attachment B shall not apply with respect to any payments made by the Five Settlement Funds to the Opt-Out Medicare-Entitled or Opt-Out GHP-Entitled Claimant and shall not bind CMS, the Medical Lienholder, or the Claimant or his or her attorney, in any individual negotiation or resolution of the amount owed CMS or the Medical Lienholder by the Claimant.

The Tort Trustee and the MPS Settlement Fund Administrator shall withhold all distributions to Medicare-Entitled Claimants and GHP-Entitled Claimants who timely submit a Timely Notice of Lien Opt-Out until CMS and/or the appropriate Participating Lienholder who has asserted a lien against a GHP-Entitled Claimant

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provides the Tort Trustee and/or the MPS Settlement Fund Administrator with written confirmation that the Claimant's Medicare claim and/or medical lien is resolved, including what portion, if any, of the Settlement Payment(s) to the Claimant shall be remitted to CMS and/or the Participating Lienholder.

A. Opt-Out Medicare-Entitled Claimants: Pursuant to Section IV.C. of this agreement, the NECC Tort Trustee shall provide Opt-Out Medicare-Entitled Claimant data to CMS in order to initiate recovery cases with the Benefit Coordination & Recovery Center ("BCRC"). The Tort Trustee will also provide electronic copies of each Opt-Out Medicare Entitled Claimant's opt out letter, which will include attorney contact information and the Medicare Entitled Claimant's signature. This document will serve as proof of representation to permit the BCRC to issue copies of correspondence to the attorney identified by the Medicare-Entitled Claimant. To the extent that Medicare-Entitled Claimants who submit a Timely Notice of Lien Opt-Out have not been contacted by BCRC to address CMS recovery claims within 30 calendar days of the NECC Tort Trustee providing to CMS the requisite data points set forth above, a Claimant who has opted-out (or his/her attorney) may contact the Tort Trustee who, in turn, will communicate with CMS to resolve the issue. (The Tort Trustee may designate to Medicare-Entitled Claimants an agent to carry out these duties). Once the recovery case is initiated by BCRC, attorneys may continue to work directly with BCRC to resolve an Opt-Out Medicare-Entitled Claimant's recovery claim. The process will include obtaining a Conditional Payment Notice ("CPN"), providing BCRC with final settlement details, and obtaining a recovery demand letter from CMS. In the event that CMS receives payment for an Opt-Out Medicare Claimant's recovery claim and must subsequently issue a refund, CMS will issue such refund to the Opt-Out Medicare Entitled Claimant as the payee, regardless of whether the NECC Tort Trustee was the payor. Opt-Out Medicare-Entitled Claimants shall present the recovery demand letter to the Tort Trustee and/or the MPS Settlement Fund Administrator before any Settlement Payments are made to the Claimant from the Five Settlement Funds. The amounts indicated on the recovery demand letter shall be withheld from all Settlement Payment(s) to the Claimant for payment to CMS. If there have been no other medical liens asserted by a Medical Lienholder, once the amounts indicated on the recovery demand letter have been retained and/or paid to CMS, the remainder of any payments due to the Claimant may be distributed to the claimant and/or his or her agents or attorneys.

B. Court Approval and NECC Tort Trustee Notice of Right to Opt-Out: This Agreement is contingent upon approval of this Agreement by the MDL Court and, for purposes only of MPS settling parties, the MPS Court. Within thirty days of such approval, the Tort Trustee shall notify Claimants who are entitled to opt-out and whose

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claims have been finally approved for payments from the Five NECC Settlement Funds that they have the right to file a Notice of Opt Out.

C. Medicare Opt-Out Status Reporting: On a weekly basis in 2016 and on a monthly basis thereafter, the Tort Trustee shall then provide a report (the "Medicare Opt-Out Status Report(s)") to counsel for the United States and the MPS Settlement Fund Administrator that includes the following information for each known Opt-Out Medicare-Entitled Claimant to date: first and last names, date of birth, gender, social security number, Medicare health insurance claim number (if known), address, claim category, amount(s) awarded to date from the National Settlement, date of correspondence offering opt-out (if applicable), date when the opt-out was postmarked, and the name and address of the attorney representing each Medicare-Entitled Claimant (if represented).

D. GHP Opt-Out Status Reporting: On a monthly basis, the Tort Trustee shall provide a report (the "GHP Opt-Out Status Report(s)") to counsel for the appropriate Participating Lienholders and the MPS Settlement Fund Administrator that includes the following information for each respective known GHP-Entitled Claimant to date who filed a Timely Notice of Lien Opt Out: name(s), date of birth, social security number, address, claim category amount(s) awarded to date from the National Settlement, and the name and address of the attorney representing each opt-out GHP-Entitled Claimant (if represented).

V. **Releases**

A. The United States releases the NECC Tort Trustee, the MPS Settlement Fund Administrator, MPS Class Counsel, MPS Defendants, NECC, the Other Settling Defendants, and the Medicare-Entitled Claimants who do not file a Timely Notice of Lien Opt Out and upon whose behalf a payment(s) has been made to the United States, as well as their attorneys, agents, successors, executors, administrators, assigns, from any and all claims which the United States now has or which may hereafter accrue under the MSP Statute, 42 U.S.C. § 1395y(b) to recover conditional payments made on behalf of the Medicare-Entitled Claimants (who do not file a Timely Notice of Lien Opt Out) related to payments by the Five NECC Settlement Funds or any other settlement payments for injuries associated with NECC products arising from a settlement entered into as of March 25, 2016.

Notwithstanding any other provision of this agreement, the United States specifically does not release:

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1. Any claim arising under criminal law;
2. Any criminal, civil, or administrative claims, rights, or defenses arising under Title 26, United States Code (Internal Revenue Code);
3. Any claims, rights or defenses arising under 31 U.S.C. §§ 3729 et seq. (False Claims Act); 31 U.S.C. § 3801, et seq. (Program Frauds Civil Remedies Act); 42 U.S.C. §§ 1320a-7a (Civil Monetary Penalties Statute), or any common law cause of action for fraud;
4. Any contribution or indemnity claims against entities or individuals other than the parties released by this Settlement Agreement;
5. Any obligations created by this Settlement Agreement; and
6. Any claims, rights or defenses not specifically released or relinquished in this Settlement Agreement.

B. The Participating Lienholders release the NECC Tort Trustee, the MPS Settlement Fund Administrator, MSP Class Counsel, NECC, the Other Settling Defendants, Category VII Claimants, and Claimants in National Settlement Categories I-VI who do not file a Timely Notice of Lien Opt Out, Claimants in Insight Categories I-VI who do not file a Timely Notice of Opt-Out, as well as their attorneys, agents, successors, executors, administrators, attorneys and assigns, of all GHP Released Claims.

VI. Waiver of Medigap and Part D Claims

For Claimants who do not file a timely Notice of Lien Opt Out, the Participating Lienholders agree to waive any claims and liens they may have arising from payments made under Medigap and Medicare Part D plans which resulted from personal injuries arising from the administration of NECC products.

VII. Electronic Payments and Reports

Payments due shall be made by electronic funds transfer pursuant to instructions provided to the NECC Tort Trustee and the MPS Settlement Fund Administrator by counsel for the United States, within 30 days of the end of the month in which payments accrued. On a quarterly basis, the NECC Tort Trustee and/or the MPS Settlement Fund Administrator shall submit a Post-Payment Report (attached

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hereto as Attachment D) to counsel for the United States and Medicare (CMS) providing CMS-requested information regarding payments and claimants on whose behalf the NECC Tort Trustee and/or the MPS Settlement Fund Administrator has remitted funds to the United States during that calendar quarter. The NECC Tort Trustee and the MPS Settlement Fund Administrator will use best efforts to include on the Post-Payment Report each Settling Medicare-Entitled Claimant's Medicare health insurance claim number (the number on the Medicare card). Identifying information regarding Settling Medicare-Entitled Claimants will be protected as confidential to the extent provided by federal law. Unless instructed otherwise by counsel for the United States, all reports should be provided to Cathy Burdette at the United States Department of Justice and _____ at CMS as an attachment to email with the heading "NECC Settlement Payments."

VIII. Determining Which Claimants Are Medicare-Entitled Claimants

The parties understand and agree that payments to Claimants by the NECC Tort Trustee and the MPS Settlement Fund Administrator shall be made on a rolling basis, as claims are approved and paid. The NECC Tort Trustee and the MPS Settlement Fund Administrator shall provide CMS' designated contact person with a completed spreadsheet of Claimants for each Claimant approved for payment in a particular batch, as specified on Attachment E, to receive payments before each distribution and further shall withhold payments for five days after processing each such spreadsheet so that CMS can approve the reconciliation spreadsheet (form attached at Attachment E) of the Medicare status of Claimants to receive payments. A reconciliation spreadsheet template shall be provided by CMS to the NECC Tort Trustee who shall provide a copy to the MPS Settlement Fund Administrator for its use.

Each Medicare-Entitled Claimant will be notified by the NECC Tort Trustee in the letter attached as A-1 of his or her one time opportunity to settle Medicare's claim. Each Settling Medicare-Entitled Claimant shall, by executing the applicable portion of Exhibit A-1 specifically: (i) provide his or her Medicare health insurance claim number (the number on the Medicare card); (ii) waive the right to receive a formal demand for recovery of Medicare conditional payments related to his or her receipt of Settlement Payments from the Five NECC Settlement Funds; (iii) waive the right to request a waiver of recovery pursuant to § 1870(c) of the Social Security Act (42 U.S.C. § 1395gg(c)) of the United States' claim for reimbursement of Medicare conditional payments related to his or her receipt of Settlement Payments; and (iv) waive any administrative or judicial appeal rights he or she may have with respect to the United States' claim for reimbursement of Medicare.

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IX. **Disputes**

If any dispute arises between the parties concerning this Agreement, the parties agree to attempt to resolve such dispute in good faith. If no such resolution can be agreed upon, the parties agree to present the dispute to the MDL Court (or, if the dispute involves only the MPS Settlement Fund, the MPS Court) for resolution.

X. **Notices**

- a. Notice to CMS shall be provided to:
- b. Notice to the NECC Tort Trustee shall be provided to:
- c. Notice to the MPS Settlement Fund Administrator shall be provided to:
- d. Notice to the Participating Lienholders shall be provided to appropriate Participating Lienholders at the addresses listed on Attachment F.

DEFINITIONS

1. **Bankruptcy Court** means the United States Bankruptcy Court for the District of Massachusetts, Eastern Division.
2. **Claimant(s)** means any person or estate entitled to be paid funds from one of the Five NECC settlements.
3. **Five NECC Settlement Funds** means the funds available for distribution to Claimants from the NECC National Settlement, the Insight Settlement, the Inspira Settlement, the High Point Settlement, and the MPS Settlement.
4. **GHP-Entitled Claimant(s)** means a Claimant who was covered by a group health plan (“GHP”), Part C Medicare Advantage plan, workers compensation insurance or other primary insurance at any time between September 1, 2012 and May 31, 2013, and such insurance paid medical bills resulting from personal injuries arising from the administration of NECC products. GHP-Entitled Claimant(s) does not include a Claimant who was covered by Medicaid or a Medi-Gap Plan or a Part D Plan which is not waived by a Participating Lienholder pursuant to this Settlement Agreement.
5. **GHP Released Claims** means any and all claims, actions, causes of action, demands, rights, damages, costs, loss of service expenses, and compensation whatsoever, which the Participating Lienholders now have or which may hereafter accrue related to covered items and services associated with injuries from administration of an NECC product.
6. **High Point Settlement Fund** means the fund established pursuant to the High Point Settlement Agreement approved by the Bankruptcy Court.
7. **Inspira Settlement Fund** means the fund established pursuant to the Inspira Settlement Agreement approved by the Bankruptcy Court.
8. **Insight Settlement Fund** means the fund established pursuant to the Insight Settlement Agreement approved by the Bankruptcy Court.
9. **MDL Court** means the United States District Court for the District of Massachusetts (at Boston) presiding over the matter entitled *In re: New England Compounding Pharmacy, Inc. Product Liability Litigation*, MDL Docket No. 2419, Master File No. 1:13-MD-2419.

Attachment A

10. **Medical Lienholder** means any insurance entity which has a statutory right to recovery of medical payments made on behalf of a Claimant, which resulted from personal injuries arising from the administration of NECC products, or which has asserted a valid lien for recovery of medical payments made on behalf of a Claimant which resulted from personal injuries arising from the administration of NECC products. Anti-Subrogation state laws in Arizona, Connecticut, Kansas, Missouri, North Carolina, New Jersey, New York and Virginia apply in making this determination.
11. **Medicare-Entitled Claimant(s)** means a Claimant who was eligible to receive Medicare benefits anytime between September 1, 2012 and May 31, 2013.
12. **MPS Class Counsel** means Marc Lipton, Rob Sickels and Marc Newman, court-appointed class counsel for the MPS Settlement. “MPS” derives from Michigan Pain Specialists.
13. **MPS Court** means the Circuit Court for the County of Livingston, State of Michigan presiding over *Adair et. al v. Michigan Pain Specialists, PLLC et. al*, Case No. 14-28156-NO.
14. **MPS Defendants** means Michigan Pain Specialists, LLC; John William Chatas; Edward Peter Washabough III, MD; Alexander George Shaloub, MD; Louis David Borjab, MD; and their insurers, Cincinnati Insurance Company and Star Insurance Company.
15. **MPS Settlement Fund** means the fund established pursuant to the MPS Settlement Agreement approved by the MPS Court.
16. **MPS Settlement Fund Administrator** means Class Action Administration LLC, 6521 West 91st Avenue, Westminster, CO 80031.
17. **NECC** means the New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center.
18. **NECC National Settlement** means the settlements with NECC, Barry Cadden, Lisa Conigliaro Cadden, Carla Conigliaro, Gregory Conigliaro, Ameridose LLC, GDC Properties Management, ARL BioPharm, Inc., Victory Mechanical Services, Inc., Liberty Industries, Inc., and their insurers., which was approved by the Bankruptcy Court in its Findings of Fact, Conclusions of Law and Order Confirming the Third Amended Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc., dated May 20, 2015.

Attachment A

19. **NECC National Settlement Administrator** means Epiq Systems, Inc., 10300 SW Allen Boulevard, Beaverton, OH 97005.
20. **NECC Tort Trustee** means Lynne Riley, court appointed trustee under the Third Amended Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc.
21. **Non-Participating Lienholders** means any Medical Lien Holder who is not a Participating Lien Holder.
22. **Other Settling Defendants** means NECC, Barry Cadden, Lisa Conigliaro Cadden, Carla Conigliaro, Gregory Conigliaro, Ameridose LLC, GDC Properties Management, ARL BioPharm, Inc., Victory Mechanical Services, Inc., Liberty Industries, Inc., High Point Surgery Center, Inspira Health Network, Inc., Insight Health Corporation, Michigan Pain Specialty, LLC, other parties that settle claims for injuries associated with NECC products, and their affiliates and insurers, under the Five NECC Settlements.
23. **Participating Lienholders** means the Medicaid Lienholders listed on Attachment F.
24. **Primary Lien** means a lien arising out of coverage pursuant to a GHP, Part C Medicare Plan, or workers compensation plan. Primary Lien does not include a claim by Medicaid for medical services or expenses or a claim by a Medi-Gap or Part D Medicare Plan, the Veteran's Administration, or Tricare.
25. **Settlement Payment or Payments** means each payment made to a Claimant from any of the Four NECC Settlements, including but not limited to any and all initial payments, final payments, or otherwise. For Claimants represented by an attorney, Settlement Payments are the gross amounts awarded before deduction for attorney fees and case expenses.

EXHIBIT B

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: NEW ENGLAND COMPOUNDING
PHARMACY, INC. PRODUCTS LIABILITY
LITIGATION

MDL No. 2419
Master Dkt. 1:13-md-02419-RWZ

THIS DOCUMENT RELATES TO:

All Actions

**[PROPOSED] ORDER ON MOTION FOR
APPROVAL OF AGREEMENT BETWEEN THE TORT TRUSTEE AND THE
CENTERS FOR MEDICARE AND MEDICAID SERVICES REGARDING
RESOLUTION OF CLAIMS FOR REIMBURSEMENT OF HEALTH CARE COSTS**

WHEREAS, the Court has reviewed the proposed agreement negotiated by and on behalf of the Tort Trustee in the NECC Bankruptcy Settlement with the Centers for Medicare and Medicaid Services (“CMS”) and attachments thereto;

WHEREAS, the agreement is still under consideration for approval by the United States Department of Justice (“DOJ”) but an expedited review and approval by this Court will expedite payments to Claimants; and

WHEREAS, the Court held a hearing on August 16, 2016 on the agreement and heard from various counsel concerning the terms of the agreement;

IT IS HEREBY ORDERED that:

1. The agreement as attached as Exhibit A to Lead Counsel’s Motion for Approval [Dkt. No. ____] is hereby approved by the Court;

2. Upon approval by the DOJ and the Circuit Court for the County of Livingston, State of Michigan, presiding over *Adair et. al v. Michigan Pain Specialist LLC et. al.* (Dkt. 14-28156-NO), (the “MPS COURT”) and finalization of the agreement as filed, the Tort Trustee,

Lead Counsel, or their designees, shall implement the terms of the agreement in order to expedite payments to Claimants as quickly as administratively possible; and

3. If the agreement is not approved by the DOJ or the MPS Court, the parties will so inform this Court immediately. If in the event the DOJ or the MPS Court insist on changes to the agreement that materially alter the terms of the agreement as presented to this Court in the August 16, 2016 hearing, the parties shall so inform the Court and seek Court approval of any material changes. If changes are required by the DOJ or the MPS Court that do not materially alter the terms of the agreement as presented to this Court in that hearing, the Tort Trustee may enter into the agreement and proceed with implementation without seeking further leave of Court.

IT IS SO ORDERED.

DATED:

Hon. Rya W. Zobel
United States District Judge

EXHIBIT C

[illegible]

EXHIBIT D

EXHIBIT A TO TORT TRUST AGREEMENT:
CLAIMS RESOLUTION FACILITY PROCEDURES

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INTRODUCTION AND GENERAL PROVISIONS

A PERSONAL INJURY AND WRONGFUL DEATH CLAIMS RESOLUTION FACILITY (the “Claims Resolution Facility”) is hereby established in accordance with the Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc. (the “Plan”) and the Tort Trust Agreement (the “Tort Trust Agreement”), the latter of which establishes the Tort Trust (the “Tort Trust”).¹

A. Among its provisions, the Plan provides for the resolution, disposition and satisfaction of the Tort Claims, as defined and identified therein, all of which Claims arise out of personal injury or death, in accordance with the Tort Trust Agreement and this Claims Resolution Facility.

B. The Tort Trust Agreement establishes the Tort Trust, the principal purpose of which is to satisfy the Tort Claims.

C. The purposes of the Claims Resolution Facility are (1) to evaluate each of the Tort Claims according to the procedures established herein, with the least practicable cost to the Trust, (2) to determine for each Allowed Tort Claim a fair and equitable compensation amount to be distributed from the Tort Trust, and (3) to effectuate such distributions as expeditiously as possible.

D. To facilitate, effectuate and implement the purposes of the Claims Resolution Facility, Epiq Class Action and Claim Solutions, Inc. (the “National Settlement Administrator”) is hereby retained and appointed to execute the functions described herein in accordance with the terms of the Trust Agreement. The National Settlement Administrator shall oversee all aspects

¹ Unless the context otherwise requires, all capitalized terms used in these Claims Resolution Facility Procedures and not otherwise defined herein shall have the meanings assigned to them in the Plan and/or the Tort Trust Agreement.

of the Claims Resolution Facility and shall prepare and distribute to the Tort Trustee periodic reports documenting the activities of the Claims Resolution Facility, including reports on Tort Claim submissions and resolution. In the event that the National Settlement Administrator resigns or is removed from office or is otherwise unable to perform the functions of the National Settlement Administrator, a successor National Settlement Administrator shall be appointed by the District Court, as defined in the Tort Trust Agreement, after notice and opportunity to be heard by persons having Tort Claims. The National Settlement Administrator shall receive reasonable compensation in an amount consistent with that of similar functionaries in similar types of proceedings and shall be reimbursed by the Tort Trust for his or her reasonable expenses, including travel expenses, reasonably required and incurred in the performance of his or her duties in accordance with the provisions of the Tort Trust Agreement and the provisions of any retention agreement between the Tort Trustee and the National Settlement Administrator. The National Settlement Administrator may employ staff as he/she deems necessary to assist him/her in the performance of his/her duties and the expenses of doing so shall be paid by the Tort Trust in accordance with the provisions of the Tort Trust Agreement and the provisions of any retention agreement between the Tort Trustee and the National Settlement Administrator. The National Settlement Administrator may also consult with the Trust Advisory Board in accordance with the provisions of the Tort Trust Agreement. The National Settlement Administrator may also retain consultants in accordance with the provisions of the Tort Trust Agreement and with the provisions of any retention agreement between the Tort Trustee and the National Settlement Administrator.

E. To provide for an appeal process from Claim denials, upon entry of an order by the District Court pursuant to 28 U.S.C. § 636, Magistrate Judge Kenneth P. Neiman will be

appointed as Appeals Administrator. If no such order is entered by the District Court within 30 days of the Plan Effective Date, then Kenneth Feinberg, Esq. will be deemed to be appointed as Appeals Administrator. In the event the Appeals Administrator resigns or is removed from office or is otherwise unable to perform the functions of the Appeals Administrator, the District Court shall appoint a successor Appeals Administrator.

F. When notice is required to be sent to a Tort Trust Beneficiary pursuant to these procedures, if the Tort Trust Beneficiary is represented by an attorney as indicated on the Tort Trust Beneficiary's NECC National Compensation Claim Form ("National Compensation Claim Form"), notice shall be provided to both the Tort Trust Beneficiary and the attorney at the addresses listed on the Tort Trust Beneficiary's National Compensation Claim Form, unless updated by the Tort Trust Beneficiary or attorney. Distributions to Tort Trust Beneficiaries who are represented by attorneys shall be made jointly to the Tort Trust Beneficiary and the attorney (or law firm). If a Tort Trust Beneficiary is not represented by an attorney, distributions shall be made payable to the Tort Trust Beneficiary.

G. It shall be the responsibility of the Tort Trust Beneficiary and/or his or her attorney to notify the National Settlement Administrator of address changes of the Tort Trust Beneficiary or the attorney and any other changes with respect to the information provided by the Tort Trust Beneficiary on a completed W-9 form.

H. To the extent that any of these Claims Resolution Facility Procedures conflicts with any provision of the Confirmation Order, the Plan, or the Tort Trust Agreement, the conflicting provision of the Confirmation Order, the Plan, or the Tort Trust Agreement, in that descending order of precedence, shall control.

PROCEDURES OF THE CLAIMS RESOLUTION FACILITY

Pursuant to the Plan and the Tort Trust Agreement, the Tort Trustee shall make distributions as per the terms of the Tort Trust Agreement and these Claims Resolution Facility Procedures. Under the Plan, Confirmation Order, Tort Trust Agreement and these Claims Resolution Facility Procedures, each Tort Trust Beneficiary whose Tort Claim is allowed shall receive his or her individually allocated distribution of the National Fund Net Trust Proceeds. Allocations shall be determined by the National Settlement Administrator, based upon the factors, methodologies and procedures set forth herein.

I. Distribution of NECC National Compensation Program Claim Forms

Within 14 days of the Effective Date, the National Settlement Administrator shall mail a National Compensation Program Claim Form, together with instructions, a Base Point Category and Adjustment Calculation Worksheet, a set of Frequently Asked Questions, and a W-9 Form to the Tort Trust Beneficiaries identified by the Tort Trustee who filed, or who had filed on their behalf, a timely Proof of Claim or Personal Injury and Wrongful Death Claim Information Form (“PITWD Addendum”) in the Chapter 11 Case.

II. Procedures for Filing National Compensation Claim Forms

A. To receive compensation from the Qualified Settlement Fund, Tort Trust Beneficiaries must submit a completed and signed National Compensation Claim Form to the National Settlement Administrator, together with all supporting documentation required, on or before [insert date 120 days after Effective Date], 2015, at 5:00 P.M., Eastern Standard Time. All National Compensation Claim Forms must be received by the National Settlement Administrator by this date and time. No National Compensation Claim Forms may be accepted by the National Settlement Administrator between this date and the date the National Settlement Administrator calculates the Tentative Point Value pursuant to Section VIII.A below, except

upon a showing of excusable neglect as determined by the National Settlement Administrator or, on appeal, to the Appeals Administrator. No National Compensation Claim Forms shall be accepted by the National Settlement Administrator after the date the National Settlement Administrator has calculated the Tentative Point Value pursuant to Section VIII.A herein, except those submitted as Resubmitted Claims pursuant to Section X.A herein. The National Settlement Administrator may also accept as timely National Compensation Claim Forms that are submitted in error (but which are otherwise timely) to the Bankruptcy Court, the District Court, or Donlin Recano.

B. The filing of a National Compensation Claim Form also constitutes participation by that Tort Trust Beneficiary's family members in the primary Tort Trust Beneficiary's Claim or the Class D Estate Claim and Class D Consortium Claims of family members shall be deemed released by the treatment afforded the primary Tort Trust Beneficiary under and in accordance with these Claims Resolution Facility Procedures.

III. Determination of Eligible Claims Based on Previously Submitted Proofs of Claims or PITWD Addenda in the NECC Bankruptcy Case and a Completed W-9 Form

A. In order to be eligible to receive compensation from the Tort Trust, a Tort Trust Beneficiary must have previously filed in the Chapter 11 Case a timely Proof of Claim or PITWD Addendum, or had a timely Proof of Claim or PITWD Addendum filed on his or her behalf (the Proof of Claim and PITWD Addenda so filed, collectively, "Timely Proofs of Claim or PITWD Addenda"). Proofs of Claim or PITWD Addenda that were allowed by the Bankruptcy Court to be filed after the Bar Date will be deemed to be Timely Proofs of Claim and PITWD Addenda.

B. The National Settlement Administrator shall conduct an initial review of all National Compensation Claim Forms and the Timely Proofs of Claim and PITWD Addenda filed

by or on behalf of each Tort Trust Beneficiary. If no Timely Proof of Claim or PITWD Addendum was filed by or on behalf of a given Tort Trust Beneficiary, the National Settlement Administrator shall make a final determination denying that Tort Trust Beneficiary's Tort Claim and shall notify the Tort Trust Beneficiary of such final denial and the procedure to appeal to the Appeals Administrator. Notwithstanding anything contained herein to the contrary, a Tort Trust Beneficiary receiving such a final denial may file an appeal with the Appeals Administrator in accordance with the provisions of Section XI below.

C. While conducting the initial review described in Section III.B., herein, the National Settlement Administrator shall also determine if the Tort Trust Beneficiary submitted a completed W-9 form with his or her National Compensation Claim Form. If a completed W-9 form was not submitted by a Tort Trust Beneficiary, the National Settlement Administrator shall notify the Tort Trust Beneficiary that one must be submitted within 90 days of such notice or the claim will be finally denied. In the event of such a final denial, the National Settlement Administrator shall notify the Tort Trust Beneficiary of the final denial and the procedure to appeal to the Appeals Administrator. Notwithstanding anything contained herein to the contrary, a Tort Trust Beneficiary receiving such a final denial may file an appeal with the Appeals Administrator in accordance with the provisions of Section XI herein.

D. All Tort Claims not denied for lack of a Timely Proof of Claim, PITWD Addendum or lack of a completed W-9 form shall be deemed to be "Eligible Claims" and persons holding such Eligible Claims shall be deemed "Eligible Tort Trust Beneficiaries."

IV. Eligible Claims Involving Injections From One or More of the Three Contaminated MPA Lots

A. Proof of Exposure to One or More of the Three Contaminated MPA Lots

In order for an Eligible Claim to qualify for any of the seven Base Point Categories described in Section IV.B herein (and thus to be deemed a “Qualified Claim”), the Eligible Tort Trust Beneficiary must submit to the National Settlement Administrator medical or other records documenting that the Tort Trust Beneficiary received an injection or injections from one or more of lots 05212012@68, 06292012@26 or 08102012@51 (the “Three Contaminated MPA Lots”) of preservative-free methylprednisolone acetate (“MPA”) compounded by New England Compounding Pharmacy (“NECC”), *i.e.* a letter from pain clinic, hospital or doctor’s office informing the Tort Trust Beneficiary that he/she had received an injection from one of the Three Contaminated MPA Lots. Alternatively, if the Eligible Tort Trust Beneficiary (on the National Compensation Claim Form) has requested that the National Settlement Administrator review the lists of patients who received an injection from one of the Three Contaminated MPA Lots that clinics, hospitals and doctor’s offices submitted to the Chapter 11 Trustee pursuant to the *Interim Order Regarding Chapter 11 Trustee’s Motion for an Order Establishing Bar Dates for Filing Proofs of Claim and for Related Relief Concerning Notice by Notice Intermediaries* [Bankr. Dkt. No. 412] (the “Patient Lists”), and the states’ lists of NECC death, stroke, fungal meningitis, spinal or paraspinal infection and/or peripheral joint infection cases (the “State NECC Lists”), and if these lists are available to the National Settlement Administrator, the National Settlement Administrator shall review the relevant Patient List(s) and State NECC lists in order to determine if the Tort Trust Beneficiary’s name is on one of such lists. If the Tort Trust Beneficiary’s name was listed on any such list, this will provide the necessary proof of injection from one of the Three Contaminated MPA Lots.

B. The Seven Base Point Categories

Eligible Tort Trust Beneficiaries who establish that they received an injection or injections from one or more of the Three Contaminated MPA Lots may apply for one of the following seven disease or medical condition categories (“Base Point Categories”):

1. Death After MPA Injection and (1) Spinal or Paraspinal Fungal Infection (including vertebral osteomyelitis, discitis, sacroiliitis, epidural or paraspinal phlegmon, epidural or paraspinal abscess and/or arachnoiditis) And/Or (2) Fungal Meningitis (“CATEGORY I”);
2. Non-Death Fungal Meningitis and Spinal or Paraspinal Fungal Infection (including vertebral osteomyelitis, discitis, sacroiliitis, epidural or paraspinal phlegmon, epidural or paraspinal abscess and/or arachnoiditis) After MPA Injection (“CATEGORY II”);
3. Non-Death Fungal Meningitis After MPA Injection (“CATEGORY III”);
4. Non-Death Spinal or Paraspinal Fungal Infection (including vertebral osteomyelitis, discitis, sacroiliitis, epidural or paraspinal phlegmon, epidural or paraspinal abscess and/or arachnoiditis) After MPA Injection (“CATEGORY IV”);
5. Peripheral Joint (e.g. hip, knee, shoulder, elbow or ankle) Fungal Infection After MPA Injection (“CATEGORY V”);
6. Headache, Word-Finding Difficulty, Nausea/Vomiting, Fever, Neck Stiffness or Pain, Back Pain, Photophobia, Lack of Appetite, Urine Retention, Slurred Speech, Limb Weakness, Numbness, and/or Pain at Injection Site And a Lumbar Puncture, MRI or CT Guided Biopsy After MPA Injection (“CATEGORY VI”);
7. No Symptoms or No Lumbar Puncture, MRI or CT Guided Biopsy After MPA Injection (“CATEGORY VII”).

C. Additional Proof Required for CATEGORY I Claims

In order for a Qualified Claim made for CATEGORY I to be allowed, the Eligible Tort Trust Beneficiary must also submit to the National Settlement Administrator (1) a certified death certificate documenting that the death occurred after injection from one of the Three

Contaminated MPA Lots and with the immediate or underlying cause of death containing one of the following words or phrases: “meningitis,” “meningoencephalitis,” “encephalitis,” “epidural injection,” “methylprednisolone injection,” “steroid injection,” “exsereohilum,” “aspergillus,” “abscess,” or “arachnoiditis;” or (2) a certified death certificate and medical documentation of (a) a diagnosis of fungal meningitis, meningoencephalitis, or encephalitis or documentation of headache, fever, stiff neck and/or photophobia and CSF profile showing pleocytosis (>5 white blood cells, adjusting for presence of red blood cells by subtracting 1 white blood cell for every 500 red blood cells present, regardless of glucose or protein levels) after injection from one of the Three Contaminated MPA Lots; and (b) documentation that the Tort Trust Beneficiary received anti-fungal treatment; or (3)(a) a certified death certificate and medical documentation of a diagnosis of spinal or paraspinal fungal infection, including vertebral osteomyelitis, discitis, sacroiliitis, epidural or paraspinal phlegmon, epidural or paraspinal abscess, or arachnoiditis (or, for arachnoiditis, documentation of intradural clumping, abnormal thickening or unevenness of nerve roots after MRI), after spinal or paraspinal injection from one of the Three Contaminated MPA Lots (including, but not limited to, spinal facet joint injection, sacroiliac joint injection or spinal or paraspinal nerve root/ganglion block injection); and (b) documentation that the Tort Trust Beneficiary received anti-fungal treatment; or (4) a certified death certificate and medical documentation of a cerebrovascular accident/stroke (but not a transient ischemic attack only) occurring after injection from one of the Three Contaminated MPA Lots and on or before December 31, 2012; or (5) a certified death certificate and proof that the Tort Trust Beneficiary was listed on the State NECC Lists of death cases. If such proof is presented, for deaths occurring before September 30, 2013, the National Settlement Administrator shall presume that the death was the result of the MPA injection or complication(s) arising therefrom unless there is

cause to believe that the death was the result of an unrelated event (*i.e.*, auto accident, unrelated illness). For deaths occurring after September 30, 2013 and for deaths where there is a reason to believe that the death resulted from an unrelated event, a certified death certificate and such other proof deemed sufficient by the National Settlement Administrator to establish that the death was the result of the MPA injection or complication(s) arising therefrom is required. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.* the Tort Trust Beneficiary's medical records only state that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary. This presumption, as used throughout these Procedures, shall only apply for the purposes of evaluating Tort Claims under these Procedures. This presumption does not affect the calculation of the statute of limitations, statute of repose, or any other time calculation for any other purpose and does not constitute an admission or waiver of any legal position by Tort Trust Beneficiaries. If these requirements are met, the National Settlement Administrator shall award 55 base points to the Tort Trust Beneficiary.

D. Additional Proof Required for CATEGORY II Claims

In order for a Qualified Claim made for CATEGORY II to be allowed, the Eligible Tort Trust Beneficiary must also submit to the National Settlement Administrator (1)(a) medical documentation of a diagnosis of fungal meningitis, meningoencephalitis and/or encephalitis or documentation of headache, fever, stiff neck and/or photophobia and CSF profile showing

pleocytosis (>5 white blood cells, adjusting for presence of red blood cells by subtracting 1 white blood cell for every 500 red blood cells present, regardless of glucose or protein levels) after injection from one of the Three Contaminated MPA Lots, and (b) medical documentation of a diagnosis of spinal or paraspinal fungal infection, including vertebral osteomyelitis, discitis, sacroiliitis, epidural or paraspinal phlegmon, epidural or paraspinal abscess, or arachnoiditis (or, for arachnoiditis, documentation of intradural clumping, abnormal thickening or unevenness of nerve roots after MRI), after spinal or paraspinal injection from one of the Three Contaminated MPA Lots (including, but not limited to, spinal facet joint injection, sacroiliac joint injection or spinal or paraspinal nerve root/ganglion block injection); and (c) documentation that the Tort Trust Beneficiary received anti-fungal treatment, or (2) proof that the Tort Trust Beneficiary was listed on the State NECC Lists of fungal meningitis or stroke cases, and was listed on the State NECC Lists of spinal or paraspinal fungal infection cases or was listed on a state list of NECC fungal meningitis and spinal or paraspinal infection cases. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary. If such requirements are met, the National Settlement Administrator shall award 40 base points to the Tort Trust Beneficiary.

E. Additional Proof Required for CATEGORY III Claims

In order for a Qualified Claim made for CATEGORY III to be allowed, the Eligible Tort Trust Beneficiary must also submit to the National Settlement Administrator (1)(a) medical documentation of a diagnosis of fungal meningitis, meningoencephalitis and/or encephalitis or documentation of headache, fever, stiff neck and/or photophobia and CSF profile showing pleocytosis (>5 white blood cells, adjusting for presence of red blood cells by subtracting 1 white blood cell for every 500 red blood cells present, regardless of glucose or protein levels) after injection from one of the Three Contaminated MPA Lots and (b) documentation that the Tort Trust Beneficiary received anti-fungal treatment; or (2) proof that the Tort Trust Beneficiary was listed on the State NECC Lists of fungal meningitis or stroke cases. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary. If such requirements are met, the National Settlement Administrator shall award 30 base points to the Tort Trust Beneficiary.

F. Additional Proof Required for CATEGORY IV Claims

In order for a Qualified Claim made for CATEGORY IV to be allowed, the Eligible Tort Trust Beneficiary must also submit to the National Settlement Administrator (1)(a) medical documentation of a diagnosis of spinal or paraspinal fungal infection, including vertebral

osteomyelitis, discitis, sacroiliitis, epidural or paraspinal phlegmon, epidural or paraspinal abscess, or arachnoiditis (or, for arachnoiditis, documentation of intradural clumping, abnormal thickening or unevenness of nerve roots after MRI), after spinal or paraspinal injection from one of the Three Contaminated MPA Lots (including, but not limited to, spinal facet joint injection, sacroiliac joint injection or spinal or paraspinal nerve root/ganglion block), and (b) documentation that the Tort Trust Beneficiary received anti-fungal treatment; or (2) proof that the Tort Trust Beneficiary was listed on the State NECC Lists of spinal or paraspinal fungal infection cases. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary. If such requirements are met, the National Settlement Administrator shall award 20 base points to the Tort Trust Beneficiary.

G. Additional Proof Required for CATEGORY V Claims

In order for a Qualified Claim made for CATEGORY V to be allowed, the Eligible Tort Trust Beneficiary must also submit to the National Settlement Administrator medical documentation of (1)(a) a diagnosis of peripheral joint (e.g. hip, knee, shoulder, elbow or ankle) fungal infection (including, but not limited to, osteomyelitis and septic arthritis) after injection from one of the Three Contaminated MPA Lots into the osteoarticular structure of a peripheral

joint (including the bursa and peripheral nerve complex) and (b) that the Tort Trust Beneficiary received anti-fungal treatment; or (2) proof that the Tort Trust Beneficiary was listed on the State NECC Lists of peripheral joint fungal infection cases. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary. If such requirements are met, the National Settlement Administrator shall award 10 base points to the Tort Trust Beneficiary.

H. Additional Proof Required for CATEGORY VI Claims

In order for a Qualified Claim made for CATEGORY VI to be allowed, the Eligible Tort Trust Beneficiary must also submit to the National Settlement Administrator (1) contemporaneous medical records documenting that the Tort Trust Beneficiary suffered from one or more of the following symptoms: headache, word-finding difficulty, nausea/vomiting, fever, neck stiffness or pain, back pain, photophobia, lack of appetite, urine retention, slurred speech, limb weakness, numbness, and/or pain at injection site after injection from one of the Three Contaminated MPA Lots and before March 31, 2013 and (2) medical records documenting one lumbar puncture, MRI or CT guided biopsy after injection from one of the Three Contaminated MPA Lots and prior to April 30, 2013. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of

injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the Patient List(s)), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary. If such requirements are met, the National Settlement Administrator shall award 1 base point to the Tort Trust Beneficiary.

I. Additional Proof Required for CATEGORY VII Claims

There is no additional proof required for CATEGORY VII claims. All Qualified Claims for CATEGORY VII shall be allowed by the National Settlement Administrator and be awarded ½ base point.

J. Upward Adjustments to Qualified Claims

1. *Age Adjustment as of Date of Death for CATEGORY I*

For Qualified Claims awarded 55 base points under CATEGORY I, the National Settlement Administrator shall also award an additional point for each year decedent's age was less than 65 on the date of death, up to a maximum of 20 points, as evidenced by the decedent's certified death certificate.

2. *Adjustment for Dependent Children Under 18 for CATEGORY I*

For Qualified Claims awarded 55 base points under CATEGORY I, the National Settlement Administrator shall also award an additional 5 points for each dependent child under the age of 18 that the decedent had as the date of death, up to a maximum of 15 points.

- (a) For this Dependent Children Adjustment, a child is considered to have been dependent on the decedent if he or she was
- (i) Under the age of 18 as of the date of death and listed as a qualifying dependent child on the decedent's 2011 or 2012 federal income tax return; or
 - (ii) A natural or legitimate child under the age of 18 as of the date of death; or
 - (iii) An adopted child under the age of 18 as of the date of death; or
 - (iv) A stepchild under the age of 18 as of the date of death, who lived with the decedent in a regular parent-child relationship at the time of the decedent's death or did not live with the decedent because of medical reasons or to attend school or for other similar reasons; or
 - (v) Under the age of 18 as of the date of death who lived with the decedent in a regular parent-child relationship at the time of the decedent's death or did not live with the decedent because of medical reasons, to attend school or other similar reasons, and to whose support the decedent made regular and substantial contributions.
- (b) Proof that a child was under 18 as of the date of death may be provided by submitting the decedent's 2011 or 2012 federal tax return, listing the child as a dependent and listing the child's date of birth or a certified birth certificate of the child.
- (c) Proof that a child was a dependent may be provided by submitting:
- (i) a copy of the decedent's 2011 or 2012 federal tax return, listing the child as a qualifying dependent child; or
 - (ii) a certified birth certificate that indicates that a child was a natural or legitimate child of the decedent. In the event that decedent's name does not appear on the birth certificate, proof may be provided by documentation evidencing a judicial determination of support; or
 - (iii) for domestic adoptions, a copy of a revised birth certificate showing the decedent as a parent. For foreign adoptions, proof may be provided by submitting a copy of the adoption decree and, if applicable, documentation showing the child's change of name. Since rules for foreign adoptions vary by country, alternative and/or additional documentation may be required by the National Settlement Administrator; or
 - (iv) for a child that is a stepchild, a certificate of marriage evidencing the marriage of the child's biological parent and the decedent, and a certified birth certificate or documentation evidencing a judicial determination of support and a statement from a person with direct knowledge that verifies that the stepchild (or stepchildren) lived with the decedent in a regular parent-child relationship at the time of the

- decedent's death or describing the reasons why the stepchild did not live with the decedent (such as for medical reasons, to attend school, or for other similar reasons); or
- (v) if dependency is claimed on the basis of the decedent having made regular and substantial contributions to the support of the child, a signed statement from a person with direct knowledge that verifies that the child (or children) lived with the decedent in a regular parent-child relationship at the time of the decedent's death or describing the reason(s) why the child did not live with the decedent (such as for medical reasons, to attend school, or for other similar reason) and one or more of the following proofs:
- evidence of eligibility as a dependent child for benefits under State or Federal programs;
 - cancelled checks, money orders, or receipts for periodic payments received from the decedent for or on behalf of the child;
 - evidence of goods or services that show regular contributions of considerable value by the decedent for or on behalf of the child; or
 - proof of coverage of the child as a family member under the decedent's Federal Employees Health Benefits enrollment or private health insurance.

3. *Spousal Adjustment for CATEGORY I*

For Qualified Claims awarded 55 base points under CATEGORY I, the National Settlement Administrator shall also award an additional 5 points if the decedent was married on as the date of death as evidenced by the decedent's certified death certificate.

4. *Adult Children Adjustment for CATEGORY I*

For Qualified Claims awarded 55 base points under CATEGORY I, the National Settlement Administrator shall also award an additional 3 points for each surviving natural or adopted adult child as of the date of death, up to a maximum of 9 points, provided that the Eligible Tort Trust Beneficiary lists the name, date of birth and current address of each surviving natural or adopted adult child on the National Compensation

Claim Form and submits a copy of the decedent's obituary that identifies the surviving natural or adopted adult child(ren) or a signed statement from a person with direct knowledge that the decedent was survived by a natural or adopted adult child(ren) and identifies the surviving child(ren).

5. *Surgical Debridement or Irrigation Surgery, Laminectomy, Discectomy or Hemilaminectomy Adjustment for CATEGORIES I, II and IV*

For Qualified Claims awarded 55 base points under CATEGORY I, 40 base points under CATEGORY II, or 20 base points under CATEGORY IV, the National Settlement Administrator shall also award an additional 2 points for each separate and distinct debridement and/or irrigation surgery without a laminectomy, discectomy or hemilaminectomy, and an additional 4 points for each separate laminectomy, discectomy or hemilaminectomy whether performed contemporaneously with a debridement and/or irrigation surgery or not (if any laminectomy, discectomy or hemilaminectomy involves multiple vertebral levels, the National Settlement Administrator shall also award an additional 2 points for that surgery), after injection from one of the Three Contaminated MPA Lots, up to a maximum of 8 points, provided that the Tort Trust Beneficiary submits to the National Settlement Administrator medical records documenting each of such surgery(ies) and/or procedure(s) after injection. Medical records documenting an incision, drainage or washout shall suffice as proof of a surgical debridement or irrigation surgery. The National Settlement Administrator shall presume that all such surgical debridements and irrigation surgeries after injection from one of the Three Contaminated MPA Lots are the result of the MPA injection or complication(s) arising therefrom. The National Settlement Administrator shall presume that each laminectomy, discectomy and hemilaminectomy procedure occurring after injection and before September 30, 2013 is

related to the MPA injection or complication(s) arising therefrom. For laminectomies, discectomies and hemilaminectomies occurring after September 30, 2013, proof deemed sufficient by the National Settlement Administrator that such procedure(s) was the result of the MPA injection or complication(s) arising therefrom is required. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

6. *Anti-Fungal Complication Adjustment for CATEGORIES I, II, III, IV, V and VI*

For Qualified Claims that are awarded 55 base point under CATEGORY I, 40 base points under CATEGORY II, 30 base points under CATEGORY III, 20 base points under CATEGORY IV, 10 base points under CATEGORY V, or 1 base point under CATEGORY VI, the National Settlement Administrator shall also award an additional 3 points if the Tort Trust Beneficiary suffered acute renal insufficiency after treatment with amphotericin B, or 5 points if the Tort Trust Beneficiary suffered acute renal insufficiency requiring temporary dialysis after treatment with amphotericin B, or 10 additional points if the Tort Trust Beneficiary suffered acute renal insufficiency requiring permanent dialysis after treatment with amphotericin B; an additional 5 points if the Tort Trust Beneficiary suffered liver injury/toxicity after treatment with voriconazole,

posaconazole, itraconazole and/or isavuconazole, or 10 points if the Tort Trust Beneficiary suffered liver injury/toxicity requiring liver transplant or placement on the waiting list for a liver transplant after treatment with voriconazole, posaconazole, itraconazole and/or isavuconazole; an additional 5 points if the Tort Trust Beneficiary suffered skin cancer after treatment with voriconazole; and an additional 3 points if the Tort Trust Beneficiary suffered periostitis after treatment with voriconazole provided that the Tort Trust Beneficiary submits medical records documenting (a) acute renal insufficiency within 30 days of the first treatment with amphotericin B, (b) acute renal insufficiency within 30 days of the first treatment with amphotericin B requiring treatment by dialysis (either temporary or permanent) within 180 days of the last treatment with amphotericin B, (c) liver injury/toxicity within 30 days of the first treatment with voriconazole, posaconazole, itraconazole and/or isavuconazole, (d) liver injury/toxicity within 30 days of the first treatment with voriconazole, posaconazole, itraconazole and/or isavuconazole requiring liver transplantation or that the Tort Trust Beneficiary was placed on the waiting list for a liver transplant within 180 days of the last treatment with voriconazole, posaconazole, itraconazole and/or isavuconazole, (e) skin cancer within 90 days of the last treatment with voriconazole as evidenced by biopsy, and/or (f) periostitis after treatment with voriconazole. Proof of acute renal insufficiency shall consist of medical records documenting a glomerular filtration rate (“GFR”) of <30 within 30 days following treatment with amphotericin B. The applicable GFR score is the GFR score listed for the patient’s race (non-African American or African American). If GFR scores are not available, medical records documenting a Creatinine Clearance (“CrCl”) level of <30 within 30 days after the first treatment with amphotericin B is

sufficient. Proof of liver injury/toxicity shall consist of medical records documenting a minimum of 5x upper limit of normal (“ULN”) elevation in either the AST or ALT test within 30 days after the first treatment with voriconazole, posaconazole, itraconazole and/or isavuconazole.

7. *Lengthy Anti-Fungal Treatment Adjustment for CATEGORIES I, II, III, IV and V*

For Qualified Claims awarded 55 base points under CATEGORY I, 40 base points under CATEGORY II, 30 base points under CATEGORY III, 20 base points under CATEGORY IV, or 10 base points under CATEGORY V, the National Settlement Administrator shall also award an additional 2 points if, after injection from one of the Three Contaminated MPA Lots, the Tort Trust Beneficiary was treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for 91 -150 days, an additional 3 points if, after injection from one of the Three Contaminated MPA Lots, the Tort Trust Beneficiary was treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for 151 -210 days, an additional 4 points if, after injection from one of the Three Contaminated MPA Lots, the Tort Trust Beneficiary was treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for 211 -270 days, an additional 5 points if, after injection from one of the Three Contaminated MPA Lots, the Tort Trust Beneficiary was treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for 271 -330 days, an additional 6 points if, after injection from one of the Three Contaminated MPA Lots, the Tort Trust Beneficiary was treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for 331-390 days, an additional 7 points if, after injection from one of the Three Contaminated MPA Lots, the Tort Trust Beneficiary was

treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for 391-450 days, an additional 8 points if, after injection from one of the Three Contaminated MPA Lots, the Tort Trust Beneficiary was treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for 451-510 days, an additional 9 points if, after injection from one of the Three Contaminated MPA Lots, the Tort Trust Beneficiary was treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for 511-570 days, or an additional 10 points if, after injection from one of the Three Contaminated MPA Lots, the Tort Trust Beneficiary was treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for more than 570 days, provided that the Tort Trust Beneficiary submits medical records documenting the length of treatment with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole after the MPA injection. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

8. *Lengthy Hospitalization Adjustment for CATEGORIES I, II, III, IV and V*

For Qualified Claims awarded 55 base points under CATEGORY I, 40 base points under CATEGORY II, 30 base points under CATEGORY III, 20 base points

under CATEGORY IV, or 10 base points under CATEGORY V, the National Settlement Administrator shall also award an additional ½ point, following 5 nights of hospitalization in an acute care hospital after injection from one of the Three Contaminated MPA Lots, for each night of inpatient stay at an acute care hospital, long-term acute care, rehabilitation, hospice or nursing home facility up to 30 nights and 1/3 point for each additional night in excess of 30 nights up to a maximum of 25 points provided that the Eligible Tort Trust Beneficiary submits to the National Settlement Administrator hospital or facility records documenting at least 5 nights of inpatient hospitalization at an acute care hospital and/or records documenting the number of additional nights the decedent stayed in an inpatient acute care hospital, long-term acute care, rehabilitation, hospice or nursing home facility as a result of the MPA injection or complication(s) arising therefrom. The National Settlement Administrator shall presume that each such night of hospitalization or facility stay occurring after injection and before September 30, 2013 was the result of the MPA injection or complication(s) arising therefrom unless there is cause to believe that the hospitalization or facility stay was the result of an unrelated event (*i.e.* auto accident, unrelated illness). For hospitalizations or facility stays for which there is reason to believe are unrelated to the MPA injection or complications arising therefrom and for those occurring after September 30, 2013, proof deemed sufficient by the National Settlement Administrator that the hospitalization or facility stay was the result of the MPA injection or complication(s) arising therefrom is required. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state

only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

9. *Multiple Lumbar Punctures and/or CT Guided Biopsies Adjustment for CATEGORIES I, II, III, IV, V and VI*

For Qualified Claims awarded 55 base points under CATEGORY I, 40 base points under CATEGORY II, 30 base points under CATEGORY III, 20 base points under CATEGORY IV, 10 base points under CATEGORY V or 1 base point under CATEGORY VI, the National Settlement Administrator shall also award an additional $\frac{1}{2}$ point for each additional lumbar puncture and/or CT guided biopsy more than one after injection from one of the Three Contaminated MPA Lots and before September 30, 2013, up to a maximum of 4 points, provided that the Tort Trust Beneficiary submits to the National Settlement Administrator medical records documenting two or more lumbar punctures and/or CT guided biopsies after injection and before September 30, 2013. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after

the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

10. *Income Adjustment for CATEGORIES I, II, III, IV and V*

For Qualified Claims awarded 55 base points under CATEGORY I, 40 base points under CATEGORY II, 30 base points under CATEGORY III, or 20 base points under CATEGORY IV, or 10 base points under CATEGORY V, the National Settlement Administrator shall also award an additional 1 point if the Tort Trust Beneficiary's 2012 or 2013 earned income was 10% to 19% less than their 2011 earned income, an additional 2 points if the Tort Trust Beneficiary's earned income was 20% to 29% less than their 2011 earned income, an additional 3 points if the Tort Trust Beneficiary's earned income was 30% to 39% less than their 2011 earned income, an additional 4 points if the Tort Trust Beneficiary's earned income was 40% to 49% less than their 2011 earned income, an additional 5 points if the Tort Trust Beneficiary's earned income was 50% to 59% less than their 2011 earned income, an additional 6 points if the Tort Trust Beneficiary's earned income was 60% to 69% less than their 2011 earned income, an additional 7 points if the Tort Trust Beneficiary's earned income was 70% to 79% less than their 2011 earned income, an additional 8 points if the Tort Trust Beneficiary's earned income was 80% to 89% less than their 2011 earned income, or an additional 9 points if the Tort Trust Beneficiary's earned income was 90% or more less than their 2011 earned income, provided that the Eligible Tort Trust Beneficiary submits to the National Settlement Administrator, the Tort Trust Beneficiary's income tax return for 2011 (whether filed jointly or single) or the Tort Trust Beneficiary's 2011 W-2(s), 1099(s) and/or 10-K(s), and the same documentation for either of the years 2012 or 2013. Earned

income shall include wages, salaries, tips, and other taxable employee pay (Form 1040, line 7), business income or loss (Form 1040, line 12), partnership or S corporation income (Form 1040, line 17), and other income (Form 1040, line 21). For CATEGORY I Qualified Claims, if the death occurred during 2012, earned income for 2013 will be deemed to be zero and no documentation of decedent's 2013 income will be required. The National Settlement Administrator shall presume that the decrease in earned income is the result of the MPA injection or complication(s) arising therefrom unless there is cause to believe that the decrease in earned income was the result of an unrelated event (*i.e.* layoff, forced work reduction, planned retirement).

11. *Stroke Adjustment for CATEGORIES II and III*

For Qualified Claims awarded 40 base points under CATEGORY II or 30 base points under CATEGORY III, the National Settlement Administrator shall also award an additional 12 points to any Tort Trust Beneficiary who suffered a cerebrovascular accident/stroke (but not a transient ischemic attack only) after injection from one of the Three Contaminated MPA Lots provided that the Tort Trust Beneficiary submits to the National Settlement Administrator medical records documenting a diagnosis of cerebrovascular accident/stroke (but not a transient ischemic attack only). If the cerebrovascular accident/stroke occurred on or before December 31, 2012, the National Settlement Administrator shall presume that the cerebrovascular accident/stroke was the result of the MPA injection or complication(s) arising therefrom unless there is a reason to believe that the cerebrovascular accident/stroke was the result of an unrelated event (*i.e.* the Tort Trust Beneficiary has a past history of cerebrovascular/accident/stroke). For cerebrovascular accidents/strokes for which there is reason to believe are unrelated to the

MPA injection or complications arising therefrom and for those occurring after December 31, 2012, proof deemed sufficient by the National Settlement Administrator that the cerebrovascular accident/stroke was the result of the MPA injection or complication(s) therefrom is required. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

12. *Sacroiliac Joint Adjustment for CATEGORIES II and IV*

For Qualified Claims awarded 40 base points under CATEGORY II or 20 base points under CATEGORY IV, the National Settlement Administrator shall also award an additional 4 points if the Tort Trust Beneficiary suffered a fungal infection of a sacroiliac joint or surrounding ligaments/bones after injection from one of the Three Contaminated MPA Lots provided that the Tort Trust Beneficiary submits to the National Settlement Administrator medical records documenting the MPA injection into a sacroiliac joint or surrounding ligaments/bones and that the fungal infection occurred in a sacroiliac joint or surrounding ligaments/bones after the MPA injection. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort

Trust Beneficiary's medical records state only that a steroid was administered on specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

13. *Arachnoiditis Adjustment and Neurogenic Bowel and/or Bladder Sub-Adjustment for CATEGORIES II and IV*

For Qualified Claims awarded 40 base points under CATEGORY II or 20 base points under CATEGORY IV, the National Settlement Administrator shall also award an additional 10 points if the Tort Trust Beneficiary suffered from arachnoiditis after injection from one of the Three Contaminated MPA Lots provided that the Tort Trust Beneficiary submits to the National Settlement Administrator medical records documenting (a) a diagnosis of arachnoiditis or documentation of intradural clumping, abnormal thickening or unevenness of nerve roots after MRI after injection from one of the Three Contaminated MPA Lots, and (b) documentation that the Tort Trust Beneficiary received anti-fungal treatment. In addition, for Qualified Claims that are awarded 10 points for arachnoiditis, the National Settlement Administrator shall also award an additional 2 points if the Tort Trust Beneficiary suffered from neurogenic bowel and/or neurogenic bladder dysfunction after injection from one of the Three Contaminated MPA Lots, provided that the Tort Trust Beneficiary submits to the National Settlement Administrator medical records documenting a diagnosis of neurogenic bowel and/or neurogenic bladder after September 1, 2012 and before December 31, 2013 and (a) in the case of neurogenic bowel, manifestation of symptoms

including significant constipation, fecal incontinence, fecal impaction, and/or alternating diarrhea lasting for more than 6 months, or (b) in the case of neurogenic bladder, manifestation of symptoms of urinary retention and/or urinary incontinence lasting more than 6 months and which required intermittent or regular urinary catheterization. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

14. *Vertebral Osteomyelitis Adjustment for CATEGORIES II and IV*

For Qualified Claims awarded 40 base points under CATEGORY II or 20 base points under CATEGORY IV, the National Settlement Administrator shall also award an additional 5 points if the Tort Trust Beneficiary suffered from vertebral osteomyelitis after injection from one of the Three Contaminated MPA Lots provided that the Tort Trust Beneficiary submits to the National Settlement Administrator medical records documenting (a) a diagnosis of vertebral osteomyelitis after injection from one of the Three Contaminated MPA Lots and (b) documentation that the Tort Trust Beneficiary received anti-fungal treatment. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical

records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

15. Peripheral Joint Infection Adjustment for CATEGORIES II, III and IV

For Qualified Claims awarded 40 base points under CATEGORY II, 30 base points under CATEGORY III, or 20 base points under CATEGORY IV, the National Settlement Administrator shall also award an additional 3 points if the Tort Trust Beneficiary also suffered from a peripheral joint fungal infection after injection from one of the Three Contaminated MPA Lots provided the Tort Trust Beneficiary submits to the National Settlement Administrator medical records documenting (a)(i) a diagnosis of peripheral joint fungal infection (including, but not limited to, osteomyelitis and septic arthritis) after injection from one of the Three Contaminated MPA Lots into the osteoarticular structure of a peripheral joint (including the bursa and peripheral nerves) and (ii) that the Tort Trust Beneficiary received anti-fungal treatment, or (b) proof that the Tort Trust Beneficiary was listed on the a state list of NECC's peripheral joint infection cases. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall

presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

16. *Hip Infection Adjustment for CATEGORY V*

For Qualified Claims awarded 10 base points under CATEGORY V, the National Settlement Administrator shall also award an additional 8 points if the Tort Trust Beneficiary's fungal infection occurred in the hip/bursa after injection from one of the Three Contaminated MPA Lots into the hip/bursa provided that the Tort Trust Beneficiary submits to the National Settlement Administrator medical records documenting that the Tort Trust Beneficiary received a MPA injection in the hip/bursa and that the fungal infection occurred in the hip/bursa after the injection. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

17. *Multiple Joint Fungal Infections Adjustment for CATEGORY V*

For Qualified Claims awarded 10 base points under CATEGORY V, the National Settlement Administrator shall also award an additional 4 points for each additional

peripheral joint fungal infection after injection from one of the Three Contaminated MPA Lots into an additional peripheral joint, up to a maximum of 8 points, provided that the Tort Trust Beneficiary submits to the National Settlement Administrator medical records documenting a diagnosis of a fungal infection of an additional peripheral joint (including, but not limited to, osteomyelitis and septic arthritis) after injection into the osteoarticular structure of the additional peripheral joint (including the bursa and the peripheral nerves). If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

18. *Debridement/Incision Surgery Adjustment for CATEGORY V*

For Qualified Claims awarded 10 base points under CATEGORY V, the National Settlement Administrator shall also award an additional 2 points for each separate and distinct (1) debridement/incision of a joint and/or associated bursa, with or without prosthesis placement; (2) an additional 3 points for each distinct synovectomy, whether or not performed contemporaneously with a debridement and/or irrigation surgery; and /or (3) an additional 4 points for each partial or full arthroplasty with or without prosthesis placement, whether or not performed contemporaneously with a debridement

and/or irrigation surgery or a synovectomy, after injection of one or more of the Three Contaminated MPA Lots into a peripheral joint, up to a maximum of 8 points, provided that the Tort Trust Beneficiary submits to the National Settlement Administrator medical records documenting such surgery(ies) and/or procedure(s) after injection from one of the Three Contaminated MPA Lots. Medical records documenting an irrigation, drainage or washout shall suffice for a debridement/incision surgery. The National Settlement Administrator shall presume that all debridement/incision surgeries after injection from one of the Three Contaminated MPA Lots are the result of the MPA injection or complication(s) arising therefrom. The National Settlement Administrator shall presume that each such synovectomy or arthroplasty procedure occurring after injection and before September 30, 2013 is related to the MPA injection or complication(s) arising therefrom. For synovectomies and arthroplasties occurring after September 30, 2013, proof deemed sufficient by the National Settlement Administrator that such procedure(s) was the result of the MPA injection or complication(s) arising therefrom is required. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the State NECC Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

19. *Hospitalization Adjustment for CATEGORY VI*

For Qualified Claims awarded 1 base point under CATEGORY VI, the National Settlement Administrator shall also award an additional ½ point for each night the Tort Trust Beneficiary was hospitalized at an acute care hospital after injection of one of the Three Contaminated MPA Lots and before April 30, 2013, up to a maximum of 3 points, provided that the Tort Trust Beneficiary submits to the National Settlement Administrator hospital records documenting the number of nights hospitalized at an acute care hospital after injection and before April 30, 2013. The National Settlement Administrator shall presume that each such hospitalization was the result of the MPA injection or complication(s) arising therefrom unless there is cause to believe that the hospitalization was the result of an unrelated event (*i.e.*, auto accident, unrelated illness). For those hospitalizations for which there is reason to believe were the result of an unrelated event, proof deemed sufficient by the National Settlement Administrator that the hospitalization was the result of the MPA injection or complication(s) arising therefrom is required. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the Patient Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

20. *Anti-Fungal Treatment Adjustment for CATEGORY VI*

For Qualified Claims awarded 1 base point under CATEGORY VI, the National Settlement Administrator shall also award an additional 1 point if, after injection from one of the Three Contaminated MPA Lots and before September 30, 2013, the Tort Trust Beneficiary was treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for 1 - 90 days, an additional 2 points if, after injection from one of the Three Contaminated MPA Lots and before September 30, 2013, the Tort Trust Beneficiary was treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for 91 - 180 days, an additional 3 points if, after injection from one of the Three Contaminated MPA Lots and before September 30, 2013, the Tort Trust Beneficiary was treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for 181 - 270 days, or an additional 4 points if, after injection from one of the Three Contaminated MPA Lots and before September 30, 2013, the Tort Trust Beneficiary was treated with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole for more than 270 days, provided that the Tort Trust Beneficiary submits medical records documenting the length of treatment with amphotericin B, voriconazole, posaconazole, itraconazole and/or isavuconazole after the MPA injection and before September 30, 2013. If the Tort Trust Beneficiary's proof of injection from one of the Three Contaminated MPA Lots does not indicate the exact date of injection from one of the Three Contaminated MPA Lots (*i.e.*, the Tort Trust Beneficiary's medical records state only that a steroid was administered on a specified date, but the Tort Trust Beneficiary's name is listed on the Patient Lists), the National Settlement Administrator shall presume that the first injection from one of the Three Contaminated MPA Lots

occurred on the first day after the first shipment of one of the Three Contaminated MPA Lots to the clinic, hospital or doctor's office that injected the contaminated MPA into the Tort Trust Beneficiary.

V. Eligible Claims Involving Other Contaminated NECC Products Apart From One of the Three Contaminated MPA Lots

A. Proof of Exposure to a Contaminated Product Compounded by NECC After January 1, 2006 Apart From One of the Three Contaminated MPA Lots

In order for an Eligible Claim that does not involve an injection or injections from one of the Three Contaminated MPA Lots to be deemed a Qualified Claim, the Eligible Tort Trust Beneficiary must submit to the National Settlement Administrator medical records or other records documenting that the Tort Trust Beneficiary was administered a specified lot of NECC product that was compounded by NECC after January 1, 2006 (*i.e.*, a letter from a clinic, hospital or doctor's office informing the Tort Trust Beneficiary that he/she was administered a specified lot of NECC product). The Tort Trust Beneficiary must also submit proof deemed sufficient by the National Settlement Administrator that the administered lot of NECC product was contaminated. Examples of such satisfactory proof are the nine lots of non-MPA NECC products which have been determined by the CDC to have been contaminated (see attached Addendum A), and NECC's outside testing laboratory's determination that some lots of NECC's products were contaminated during the summer and fall of 2012 (see attached Addendum B). If the requirements listed above are satisfied, the Tort Trust Beneficiary shall be entitled to make a claim for one of the seven Base Point Categories designed for the Three Contaminated MPA Lots described in Section IV.B herein. The Tort Trust Beneficiary must satisfy the proof requirements for one of the seven Base Point Categories and adjustments applied for, except the Tort Trust Beneficiary need not provide proof of an injection from one of the Three

Contaminated MPA Lots and references to an “injection from one of the Three Contaminated MPA Lots” in the seven Base Categories proof requirements will be read as “administration from a contaminated lot of NECC product.”

B. Claims Involving an Injection or Injections of One or More of the Three Contaminated MPA Lots and Administration of a Contaminated Lot of NECC Product Apart from One of the Three Contaminated MPA Lots

In the event that a Tort Trust Beneficiary has received both an injection or injections from one or more of the Three Contaminated MPA Lots and also has been administered another contaminated NECC product, the Tort Trust Beneficiary may apply for one of the seven Base Point Categories only for either the MPA injection(s) or for the other contaminated NECC product.

VI. Eligible Claims Involving Bacterial Infection and Bacterial Meningitis

An Eligible Tort Trust Beneficiary who claims that he/she suffered from a bacterial infection or bacterial meningitis after being administered a contaminated lot of NECC product must submit to the National Settlement Administrator medical or other records documenting that the Tort Trust Beneficiary was administered a specified lot of NECC product that was compounded after January 1, 2006 (*i.e.*, a letter from a clinic, hospital, or doctor’s office informing the Tort Trust Beneficiary that he/she had received a specified lot of NECC product). The Tort Trust Beneficiary must also submit to the National Settlement Administrator proof deemed sufficient by the National Settlement Administrator that the lot of NECC product administered to the Tort Trust Beneficiary was contaminated with a specific type of bacteria. Examples of such contaminated lots of NECC products are the six lots of non-MPA NECC products that have been determined by the CDC and FDA to have been contaminated with various specific types of bacteria (see Addendum A), Lot 09252012@50 of Bacitracin (stock) 50ku/20 MI solution that ARL found to be contaminated with *Paenibacillus borealis*, and Lot

08102012@51 of MPA that was found to be contaminated with *Bacillus subtilis* and *Bacillus pumilus*. The Tort Trust Beneficiary must also submit to the National Settlement Administrator medical or other records documenting that the Tort Trust Beneficiary was infected with the same specific type of bacteria that was found to be in the contaminated lot of NECC product administered to the Tort Trust Beneficiary (*i.e.*, *Bacillus subtilis* or *Bacillus pumilus* for MPA Lot 08102012@51). If the requirements listed above are satisfied, the Tort Trust Beneficiary shall be entitled to make a claim for one of the seven Base Point Categories designed for the Three Contaminated MPA Lots. The Tort Trust Beneficiary must satisfy the proof requirements for the one of the seven Base Point Categories and adjustments applied for subject to the following:

1. *For CATEGORY I Claims:*

- (i) the death certificate must document the immediate or underlying cause of death as “bacterial infection,” “bacterial meningoen­cephalitis,” “bacterial encephalitis,” or “bacterial meningitis,” or the medical records must document a diagnosis of bacterial infection or bacterial meningitis, bacterial meningoen­cephalitis or bacterial encephalitis after administration from a contaminated lot of NECC product. No medical documentation of fungal meningitis, fungal meningoen­cephalitis, fungal encephalitis, or spinal or paraspinal fungal infection is required. No documentation of anti-fungal treatment is required;
- (ii) there will be no Lengthy Anti-Fungal Treatment Adjustment or Anti-Fungal Complication Adjustment available.

2. *For CATEGORY II, III AND IV Claims:*

- (i) the medical records must document a diagnosis of bacterial meningitis, bacterial meningoencephalitis, bacterial encephalitis, or spinal or paraspinal bacterial infection after administration from a contaminated lot of NECC product. No medical documentation of fungal meningitis, fungal meningoencephalitis, fungal encephalitis, or spinal or paraspinal fungal infection is required. No documentation of anti-fungal treatment is required;
- (ii) for the Sacroiliac Joint Infection Adjustment, the medical records must document injection from a contaminated lot of NECC product into the sacroiliac joint or surrounding ligaments/bones and that the bacterial infection occurred in the sacroiliac joint or surrounding ligaments/bones after injection. No documentation of fungal infection in the sacroiliac joint is required;
- (iii) there will be no Lengthy Anti-Fungal Treatment Adjustment or Anti-Fungal Complication Adjustment available;
- (iv) for the Peripheral Joint Infection Adjustment, the medical records must document a peripheral joint bacterial infection after injection from a contaminated lot of NECC product into the peripheral joint. No documentation of a peripheral joint fungal infection is required.

3. *For CATEGORY V Claims:*

- (i) the medical records must document a diagnosis of a peripheral joint
(*e.g.*, hip, knee, shoulder, or ankle) bacterial infection after injection from
a contaminated lot of NECC product into the osteoarticular structure of a
peripheral joint (including the bursa and peripheral nerves). No
documentation of a peripheral joint fungal infection or of anti-fungal
treatment is required;
- (ii) for the Hip Infection Adjustment, the medical records must document a
bacterial infection in the hip/bursa after injection from a contaminated lot
of NECC product into the hip/bursa. No documentation that a fungal
injection occurred in the hip/bursa is required;
- (iii) there will be no Lengthy Anti-Fungal Treatment Adjustment or Anti-
Fungal Complication Adjustment available;
- (iv) for the Multiple Joint Fungal Infections Adjustment, the medical records
must document a bacterial infection in the additional peripheral joint after
injection from a contaminated lot of NECC product into the osteoarticular
structure of an additional peripheral joint (including the bursa and the
peripheral nerves). No documentation of a fungal infection of an
additional peripheral joint is required.

4. *For CATEGORY VI Claims:*

There will be no Anti-Fungal Treatment Adjustment or Anti-Fungal
Complication Adjustment available.

VII. Claims Assistance Program

The National Settlement Administrator shall develop, staff and maintain a program for providing claims assistance to Tort Trust Beneficiaries (“Claims Assistance Program”). This program shall be a part of the Claims Resolution Facility, staffed by employees of the Claims Resolution Facility, and is intended to provide assistance to all Tort Trust Beneficiaries regarding the Claims Resolution Facility procedures, eligibility requirements, submission requirements (including the documentation required), denials, deficiencies, the process for curing deficiencies, obtaining re-reviews, requesting reconsideration under a different Base Point Category and appeal procedures in the event of a final denial of a claim, and the status of a Tort Trust Beneficiary’s claim. The Claims Assistance Program staff shall not provide legal advice or tax advice to Tort Trust Beneficiaries.

VIII. Initial Payments On Qualified Claims

A. As soon as practicable after the Claims Deadline and after completing his/her initial review of claims, the National Settlement Administrator shall compute a tentative dollar value of each Claimed Point (“Tentative Point Value”) according to the following formula: (i) calculate the sum of all Claimed Points in all of the Eligible Claims (“Summed Points”), (ii) multiply the Summed Points by a factor of 1.5 (“Enhanced Points”), and (iii) divide the National Fund Net Trust Proceeds (*i.e.*, the amount available for distribution to Tort Trust Beneficiaries at the time the computation is made) by the number of Enhanced Points:

$$[\text{Tentative Point Value} = [\text{National Fund Net Trust Proceeds} \div \text{Enhanced Points}]]$$

B. The National Settlement Administrator shall then evaluate Tort Claims in the order that they were received.

C. If an Eligible Claim is allowed in full, the Tort Trust Beneficiary’s Claimed Points shall be deemed to be Approved Points, and the National Settlement Administrator shall multiply the Approved Points by the Tentative Point Value to determine the amount of the Initial

Payment to the Claimant. The National Settlement Administrator shall notify said Tort Trust Beneficiary of the allowance of the claim in full, the amount of Approved Points, the amount of the Initial Payment, and the amount of the Initial Payment constitutes interim compensation and that the Tort Trust Beneficiary may receive additional compensation after the Claims Process is completed and all appeals from the National Settlement Administrator's final determinations have been resolved.

D. Notwithstanding anything herein to the contrary, no distribution shall be made to a Tort Trust Beneficiary if such Tort Trust Beneficiary has not returned a signed form W-9 to the National Settlement Administrator.

E. If a completed W-9 form has been received by the National Settlement Administrator, the National Settlement Administrator shall notify the Tort Trustee of the Allowed Claim and that a check should be sent to the Tort Trust Beneficiary (or, if represented by an attorney, made payable jointly to the Tort Trust Beneficiary and the attorney or law firm and sent to the attorney) in the amount of the Initial Claim Value, subject to the provisions of the Plan and the Tort Trust Agreement.

IX. Provisional Denials

A. Eligible Claims not approved in full by the National Settlement Administrator shall be deemed to be provisionally denied ("Provisional Denials"). Provisional Denials shall consist of Eligible Claims denied in whole (*e.g.*, claim did not meet the proof requirements for a Base Point Category) or denied in part (*e.g.*, an applied-for adjustment was not awarded).

B. For each Eligible Claim denied in part, the National Settlement Administrator shall sum the Points that have been approved ("Approved Points") and determine the Initial

Claim Value of the claim as approved by multiplying the Approved Points by the Tentative Point Value.

C. A “Notice of Provisional Denial” identifying the specific reason(s) for the provisional denial and, for claims denied in part, stating the number of Approved Points and the Initial Claim Value as determined in accordance with Section IX.B herein, shall be sent to the Tort Trust Beneficiary. Such notice shall also inform the Tort Trust Beneficiary of (a) the procedures and deadlines established pursuant to Section X herein for correcting deficiencies, obtaining a re-review for error, and obtaining reconsideration under a different Base Point Category, and (b) the availability of assistance through the Claims Assistance Program. Such Notices of Provisional Denial shall inform the Tort Trust Beneficiary that if the Tort Trust Beneficiary fails to follow the procedures established pursuant to Section X below within 90 days of the Notice of Provisional Denial then the Provisional Denial will be deemed to be a final determination and the Tort Trust Beneficiary will have waived any right to appeal to the Appeals Administrator and, for claims denied in part, that the Initial Claim Value will be paid after 90 days from the date of the Notice of Provisional Denial.

D. The Notice of Provisional Denial shall also inform Tort Trust Beneficiaries that the compensation payable on any Eligible Claim that is approved, in whole or in part, after being re-submitted for reconsideration under a different Base Point Category may be reduced by the National Settlement Administrator pursuant to Section XII.B herein.

X. Attempts to Cure Deficiencies, Requesting Re-review For Error or Requesting Reconsideration Under a Different Base Point Category.

A. In the event of a Provisional Denial, a Tort Trust Beneficiary shall have ninety (90) days from the date of the Notice of Provisional Denial to submit to the National Settlement Administrator (a) documentation that purports to cure some or all of the noticed deficiencies

(“attempt to cure deficiency”), (b) a request for re-review for error, which request states fully the grounds for such request (“request for re-review for error”), or (c) a request for reconsideration under a different Base Point Category, which shall be accompanied by a new National Compensation Claim Form and all required documentation in support of the new claim (“Resubmitted Claim”). A Tort Trust Beneficiary requesting reconsideration under a different Base Category shall also write or type the following at the top of the new National Compensation Claim Form: “RE-SUBMITTED CLAIM – NEW BASE POINT CATEGORY.” All such documentation, requests and Resubmitted Claims must be received by the National Settlement Administrator by the Deadline imposed by this subsection.

B. The National Settlement Administrator shall evaluate and make a final determination on attempts to cure deficiencies and requests for re-reviews for error in the order in which they are received. A Notice of Final Determination shall then be sent to such Tort Trust Beneficiary, which Notice shall contain the following information (as applicable): (a) the National Settlement Administrator’s final determination on the Tort Trust Beneficiary’s Tort Claim, which may constitute approval in whole, approval in part, or denial in whole, and the reason(s) therefor, (b) the number of Approved Points (if any), (c) that payment of the claim (if any) will be made, subject to the provisions of the Plan and the Tort Trust Agreement, after 90 days if no appeal is sought by the Tort Trust Beneficiary pursuant to Section XI herein, (d) in the event of a denial in whole or in part, notice of the appeals procedure available pursuant to Section XI herein; and (e) the availability of assistance through the Claims Assistance Program.

C. In order to encourage the accuracy of originally-filed Tort Claims, to reduce the administrative costs to the Tort Trust of re-considering claims under different Base Point Categories, and to be able to make Initial Payments to Tort Trust Beneficiaries, the National

Settlement Administrator shall hold for review all requests for reconsideration under a different Base Point Category until all other claims (including those involving attempts to cure deficiencies and requests for re-review for error pursuant to Section X.B herein, but not claims that are appealed to the Appeals Administrator) have been finally determined. The National Settlement Administrator shall thereafter review and make a final determination on all requests for reconsideration under a different Base Point Category in the order that they were received. A Notice of Final Determination shall then be sent to such Tort Trust Beneficiaries, which notice shall contain the following information: (a) the National Settlement Administrator's final determination on the Tort Trust Beneficiary's claim, which may constitute approval in whole, approval in part, or denial in whole, and the reason(s) therefore; (b) the number of Approved Points (if any); (c) in the event of a denial in whole or in part, notice of the appeals procedure available pursuant to Section XI herein; (d) notice that any awards on requests for reconsideration under a different base point category, whether allowed in whole or in part, may be reduced pursuant to Section XII.B herein and will not be paid until the Final Payments to Tort Trust Beneficiaries have been calculated; and (e) the availability of the Claims Assistance Program.

D. In the event that a Tort Trust Beneficiary does not submit to the National Settlement Administrator, pursuant to Section X.A., herein, within ninety (90) days from the date of the Notice of Provisional Denial, an attempt to cure a deficiency, a request for re-review for error or a request for reconsideration under a different Base Point Category, the National Settlement Administrator's Provisional Denial shall automatically become a final determination and the Tort Trust Beneficiary shall have waived any right to exercise the appeal procedures set out in Section XI herein. If any such provisional denial that automatically becomes a final

determination included an award of Approved Points and an Initial Claim Value, the National Settlement Administrator shall notify the Tort Trustee of the Approved Claim and that a check should be sent to the Tort Trust Beneficiary (or, if represented by an attorney, a check made payable jointly to the Tort Trust Beneficiary and the attorney or law firm and sent to the attorney) in the amount of the Initial Claim Value for said claim subject to the provisions of the Plan and the Tort Trust Agreement.

XI. Appeals From Final Determinations

A. Any Tort Trust Beneficiary aggrieved by a final determination made by the National Settlement Administrator who has not waived the right of appeal pursuant to the provisions of Section X.D herein shall have the right to appeal such final determination to the Appeals Administrator. To be eligible for consideration by the Appeals Administrator, any such appeal must be in the form of a written statement explaining the Tort Trust Beneficiary's contentions and must be received by the Appeals Administrator on or before thirty (30) days after the date of the National Settlement Administrator's final determination. The Appeals Administrator shall notify the National Settlement Administrator of any such appeal and the National Settlement Administrator shall promptly forward to the Appeals Administrator a copy of the Tort Trust Beneficiary's claim file for each appeal.

B. For claims denied in full, the Appeals Administrator shall (1) perform a *de novo* evaluation of the denial in full in accordance with the applicable provisions of Sections III-VI herein, (2) if no upward adjustments to a Base Point Category were claimed, make a final determination as to whether the claim should be allowed and the number of Approved Points allowed for each such claim, which may be reduced by the National Settlement Administrator in accordance with Section XII.B herein for any claim that was approved after reconsideration

under a different Base Point Category, (3) if upward adjustments to a Base Point Category were claimed, make a final determination as to whether the claim should be allowed under the Base Point Category claimed, and, if such claim is so allowed, remand the matter to the Settlement Administrator to allow him or her to issue a provisional determination on the upward adjustments claimed, and (4) inform the respective Tort Trust Beneficiary and the National Settlement Administrator in writing of the action taken by the Appeals Administrator and the number of Approved Points, if any.

C. For claims denied in part, the Appeals Administrator shall (1) perform a *de novo* evaluation of the partial denial in accordance with the applicable provisions of Sections III-VI herein, (2) make a final determination of the number of Approved Points allowed for each such claim, which may be reduced by the National Settlement Administrator in accordance with Section XII.B herein for any claim that was approved after reconsideration under a Different Base Category, and (3) inform the respective Tort Trust Beneficiaries and the National Settlement Administrator in writing of such final determination and the number of Approved Points. The Appeals Administrator's final determination shall be final and binding.

XII. Final Payments to Tort Trust Beneficiaries

A. Within 120 days after all claims are finally determined, all appeals are resolved by the Appeals Administrator, and the final resolution of any appeals of the Bankruptcy Court's Confirmation Order, the National Settlement Administrator shall compute the final dollar value of each Approved Point ("Final Point Value") by dividing the Net Distribution Amount (*i.e.*, the total amount previously paid to Tort Trust Beneficiaries and the amount available to be paid in compensation to Tort Trust Beneficiaries) by the sum of (i) all Approved Points for claims approved in full pursuant to Section VIII.C herein, (ii) all Approved Points for claims finally

determined by the National Settlement Administrator pursuant to Section X.A-D herein, including those claims that were re-submitted for review under a different Base Point Category and (iii) all Approved Points for claims finally determined by the Appeals Administrator pursuant to Section XI herein.

B. In the event that the computation in Section XII.A herein yields a final dollar value of each Approved Point that is less than the Tentative Point Value, then the National Settlement Administrator shall reduce, on a *pro rata* basis, the Approved Points awarded on claims that were re-submitted for review under a different Base Point Category in such amount as is required for the computation in Section XII.A herein to yield a final dollar value of each Approved Point that is equal to the Tentative Point Value. Such final dollar shall be considered the Final Point Value.

C. In the event that the computation in Section XII.A herein yields a final dollar value of each Approved Point that is greater than the Tentative Point Value, then such final dollar value of each Approved Point shall be considered the Final Point Value.

D. The National Settlement Administrator shall then determine the final compensation amount for each Qualified Claim ("Final Compensation Amount") by multiplying the Approved Points times the Final Point Value on each Qualified Claim.

E. Promptly thereafter, the National Settlement Administrator shall notify the Tort Trustee to make the following disbursements:

1. If the Final Point Value exceeds the Tentative Point Value, then each Tort Trust Beneficiary who received an Initial Payment pursuant to Section VIII.C or X.D above shall be paid (or, if represented by an attorney, paid jointly with the attorney or law firm) an additional amount equivalent to the difference between the Tort Trust

Beneficiary's Final Compensation Amount and the Initial Payment, subject to the provisions of the Plan and the Tort Trust Agreement.

2. All other Tort Trust Beneficiaries whose Tort Claim has been approved in whole or in part shall be paid (or if represented by an attorney, paid jointly with the attorney or law firm) an amount equivalent to the Tort Trust Beneficiary's Final Compensation Amount subject to the provisions of the Plan and the Tort Trust Agreement.

F. Additional Assets Received by the Tort Trust after the Final Payments have been made to the Tort Trust Beneficiaries may be disbursed on a pro rata basis to Tort Trust Beneficiaries or otherwise, pursuant to the provisions of the Plan and the Tort Trust Agreement.

XIII. Prevention and Detection of Fraud

A. The National Settlement Administrator may institute claim auditing procedures and other procedures to detect and prevent the allowance of fraudulent claims. All claims must be signed under the pains and penalties of perjury. The submission of a fraudulent claim will violate the criminal laws of the United States, including the criminal provisions applicable to Bankruptcy Crimes, 18 U.S.C. § 152, and subject those responsible to criminal prosecution in the federal courts. If the National Settlement Administrator determines that a claim is fraudulent, the National Settlement Administrator shall deny the claim and so inform the Tort Trust Beneficiary and the Tort Trustee.

B. The National Settlement Administrator shall have the authority to request the Tort Trust Beneficiary to submit additional medical, hospital, facility or other records in order to make a determination of allowance or denial of any claim. If the Tort Trust Beneficiary refuses to or fails to respond to such a request within ninety (90) days or if the National Settlement

Administrator determines that a Tort Trust Beneficiary's response is inadequate, the National Settlement Administrator shall take such actions as he or she deems appropriate on the claim and notify the Tort Trust Beneficiary of the action and basis therefore.

C. The National Settlement Administrator may conduct random audits to verify supporting documentation submitted (including death certificates, medical and other records) by randomly selecting claims and may audit individual claims or groups of claims.

D. All Tort Trust Beneficiaries must certify to the National Settlement Administrator on the National Compensation Claim Form that the Tort Trust Beneficiary has not transferred his or her right to recover from the Released Parties with respect to his or her Claim such that the Claim can be asserted by another person or entity. The fact that a Tort Trust Beneficiary has executed a "subrogation" agreement with a health insurer or that a statutory provision grants to any governmental entity rights of subrogation shall not of itself be construed as a transfer of the Tort Trust Beneficiary's right to recover.

XIV. Closure of the Claims Resolution Facility

Within ninety (90) days after all Qualified Claims have been paid by the Tort Trust, the National Settlement Administrator shall wind up the affairs of the Claims Resolution Facility and the National Settlement Administrator and the Tort Trustee shall file a joint final report with the Bankruptcy Court and the District Court. The final report shall specify the total number of Claims filed in each of the seven Base Point Categories, the Tentative Point Value of each point, the Final Point Value of each point, the total number of Qualified Claims in each Base Point Category, the total number of points awarded in each Base Point Category, and the total amounts paid to each Tort Trust Beneficiary in each Base Point Category.

XV. Notices to the National Settlement Administrator

To be effective, all requests, notices, Claims, and Resubmitted Claims to or upon the National Settlement Administrator and/or the Claims Resolution Facility shall be in writing, and unless otherwise expressly provided herein, shall be deemed to have been duly given or made when actually delivered to the National Settlement Administrator at the address set forth below:

XVI. Notices to the Appeals Administrator

To be effective, an appeal made to the Appeals Administrator shall be in writing and, unless otherwise expressly provided herein, shall be deemed to have been duly given or made when actually delivered to the Appeals Administrator at the address set forth below:

Home Drugs Drug Safety and Availability Multistate outbreak of fungal meningitis and other infections

Drugs

Multistate outbreak of fungal meningitis and other infections



Laboratory Testing and Results

[12-12-2012] FDA and CDC have identified bacterial and/or fungal contamination in unopened vials of betamethasone, cardioplegia, and triamcinolone solutions distributed and recalled from NECC. These include bacteria known as *Bacillus*, and fungal species including *Aspergillus tubingensis*, *Aspergillus fumigatus*, *Cladosporium* species, and *Penicillium* species. Although rare, some of the identified *Bacillus* species can be human pathogens. Some of the fungal organisms identified, particularly *Aspergillus fumigatus*, are known to cause disease in humans. It is not known how product contamination with these organisms could affect patients clinically. See CDC's Advice for Clinicians¹.

CDC and FDA Laboratory-Confirmed Organisms from Product Samples		
Laboratory-Confirmed Organisms from Product Samples Associated with NECC Recalled Lots of Betamethasone, Cardioplegia, and Triamcinolone Solutions		
Medication	Lot Number	Bacterial and Fungal Contamination
Betamethasone 6 mg/mL injectable -5 mL per vial	08202012@141	<i>Paenibacillus pabuli/amolyticus</i> , <i>Bacillus idriensis</i> , <i>Bacillus flexus</i> , <i>Bacillus simplex</i> , <i>Lysinibacillus</i> sp., <i>Bacillus niacini</i> , <i>Kocuria rosea</i> , <i>Bacillus lentus</i>
Betamethasone 6 mg/mL injectable -5 mL per vial	07032012@22	<i>Bacillus niabensis</i> , <i>Bacillus circulans</i>
Betamethasone 12 mg/mL injectable - 5 mL per vial	07302012@52	<i>Bacillus lentus</i> , <i>Bacillus circulans</i> , <i>Bacillus niabensis</i> , <i>Paenibacillus barengoltzii/timonensis</i>
Betamethasone 6mg/mL injectable - 5 mL per vial	08202012@44	<i>Bacillus lentus</i> , <i>Bacillus firmus</i> , <i>Bacillus pumilus</i>
Betamethasone 6 mg/mL injectable - 5 mL per vial	08152012@84	<i>Penicillium</i> sp., <i>Cladosporium</i> sp.
Triamcinolone 40mg/mL injectable - 1 mL per vial	06062012@6	<i>Bacillus lentus</i> , <i>Bacillus circulans</i> , <i>Bacillus niabensis</i> , <i>Bacillus nealsonii</i> , <i>Bacillus subtilis</i> group, <i>Bacillus firmus</i>
Triamcinolone 40 mg/mL injectable - 2 mL per vial	08172012@60	<i>Aspergillus tubingensis</i> , <i>Penicillium</i> sp.
Triamcinolone 40mg/mL injectable - 10 mL per vial	08242012@2	<i>Aspergillus fumigatus</i>
Cardioplegia solution 265.5 mL per bag	09242012@55	<i>Bacillus halmopalus/horikoshii</i> , <i>Brevibacillus choshinensis</i>

Related Information

- FDA Form 483 for New England Compounding Center (PDF - 1.7MB)²
- Archive of Updates on Fungal Meningitis Outbreak³
- List of Recalled Products Related to Fungal Meningitis Outbreak⁴
- Meningitis Outbreak: Voriconazole and Liposomal Amphotericin B Availability Information⁵

Page Last Updated: 09/06/2013

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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 10903 New Hampshire Avenue
 Silver Spring, MD 20993
 Ph. 1-888-INFO-FDA (1-888-463-6332)
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U.S. Department of Health & Human Services

Links on this page:

1. <http://www.cdc.gov/medicationsafety/recalls/necc/#advice>
2. </downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM325980.pdf>
3. </Drugs/DrugSafety/FungalMeningitis/ucm325037.htm>
4. </Drugs/DrugSafety/ucm322752.htm>
5. </Drugs/DrugSafety/DrugShortages/ucm323947.htm>

ARL LABORATORY
CONFIRMED CONTAMINATION FROM NECC NON-MPA PRODUCT SAMPLES

Medication	Lot Number
Bacitracin 50,000 units in 20ml 0.9% Sodium Chloride	07232012@125
Polym-Bari (STOCK) 3L *Glen Falls* 1.5mu-30KU/30mL solution	08062012@115
Polymyxin/Bacitracin *Winchester* 1mu-50KU/20mL solution	08272012@87
Sodium Bicarbonate 150mEq/1000ml in Sterile Water for injection	08282012@110
Bacitracin (STOCK) 50KU/20mL solution	09252012@90
Potassium Chloride Sterile Solution Concentrate, USP 2mEq/ml (500mEq)	09252012@94